





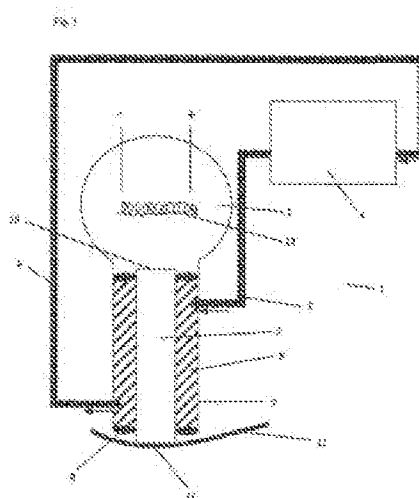
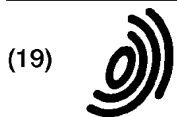


**Irradiation device, especially for photothermolysis****Publication number:** EP1038505 (A2)**Publication date:** 2000-09-27**Inventor(s):** CONRADY JUERGEN [DE]**Applicant(s):** PLASMAPHOTONICS GMBH [DE]**Classification:****- international:** **A61B18/20**; A61B18/00; A61B18/18; A61B18/22; **A61B18/20**; A61B18/00; A61B18/18; (IPC1-7): A61B18/18**- European:** A61B18/20H**Application number:** EP20000250088 20000309**Priority number(s):** DE19991014108 19990323**Also published as:** EP1038505 (A3)**Cited documents:** WO9426185 (A1) US5344418 (A) US5620478 (A) WO9319680 (A1) US2056990 (A)[more >>](#)**Abstract of EP 1038505 (A2)**

An irradiation device (1) includes a non-coherent NIR source of light (2), a light waveguide (3) assigned to this source of light and a cooling device (4). The light waveguide is designed as one piece and made from sapphire or quartz. On its perimeter there is a cooling substance in a closed cooling circuit. The cooling device has a collecting vessel for cooling liquid (9), a supply (5), an outlet (6) and a cylinder-shaped area (7) surrounding the light waveguide.



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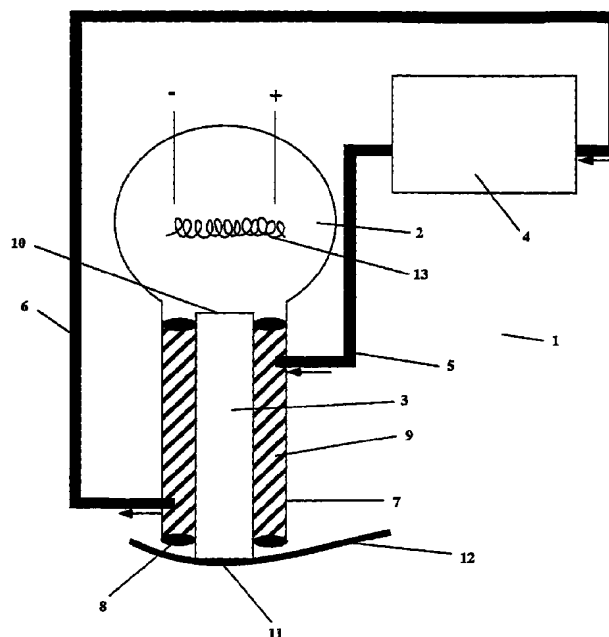
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### (54) **Bestrahlungsanordnung, insbesondere zur optischen Thermolyse**

(57) Die Erfindung betrifft eine Bestrahlungsanordnung (1), insbesondere zur optischen Thermolyse, umfassend eine nichtkohärente NIR-Lichtquelle (2), einen der NIR-Lichtquelle (2) zugeordneten Lichtwellenleiter (3) und eine Kühleinrichtung (4), wobei der Lichtwellenleiter (3) einstückig aus einem massiven Saphir oder Quarz gebildet ist, um dessen Umfang mindestens teilweise ein in einem geschlossenen Kühlkreislauf befindliches Kühlmittel sich befindet.

Fig. 1



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## Beschreibung

**[0001]** Die Erfindung betrifft eine Strahlungsanordnung, insbesondere zur optischen Thermolyse, umfassend eine nichtkohärente NIR-Lichtquelle, einen Lichtwellenleiter und eine Kühleinrichtung zur Kühlung der oberen Hautschichten und eine pulsare NIR-Lichtquelle.

**[0002]** Der spektrale Bereich zwischen ca. 700 und 1.300 nm ist für verschiedene dermatologische und auch bildgebende Anwendungen sehr interessant, da in diesem Spektralbereich eine nur noch geringe Absorption durch den Hautfarbstoff Melanin erfolgt und somit eine große Eindringtiefe der Strahlung in diesem Wellenlängenbereich gewährleistet ist. Mögliche Lichtquellen, die diesen Spektralbereich abdecken, sind Neodym-YAG-Laser sowie GaAs-Laserdioden. Darüber hinaus finden nichtkohärente Lichtquellen, wie beispielsweise Xenon-Hochdrucklampen, Verwendung.

**[0003]** Obwohl die Absorption des Blutfarbstoffs im nahen Infrarot um mehrere Größenordnungen geringer ist als im sichtbaren Bereich, sind doch die Absorptionsunterschiede zum umliegenden Gewebe so stark, daß eine selektive Erwärmung von bestimmten Gefäßen durch NIR-Strahlung möglich ist. Beispielsweise beträgt die Eindringtiefe von Nd-YAG-Strahlung bei einer Wellenlänge von 106 µm in Haut 4 mm und in Blut 0,8 mm (Berlien, Müller - Angewandte Lasermedizin II - 3.1, 33, Tab.6 I, EcoMed-Verlag 1997). Bei den interessierenden Gefäßen handelt es sich beispielsweise um erworbene Gefäßmißbildungen aus dem Varikosiskomplex (Krampfadern). Die Erwärmung des Gefäßlumens, beispielsweise durch Gefäßabsorption, führt zu einer Schädigung des Gefäßendothels. Hierdurch sinken die vom Endothel abgegebenen gerinnungshemmenden Faktoren wie Stickoxide (NO) sowie Prostazyklin (PGI<sub>2</sub>) ab. Thrombozyten lagern sich an der Gefäßwand an und bilden schließlich einen aus Erythrozyten und Thrombozyten bestehenden, das Gefäß verschließenden roten Thrombus. Jetzt fließt durch die Krampfader kein Blut mehr, und im weiteren Verlauf wird dieser Thrombus von Bindegewebe durchwachsen und somit das Gefäß verodet.

**[0004]** Bei der Behandlung oberflächlicher Gefäßveränderungen reicht es oft aus, ohne externe Kühlung auszukommen, da infolge der kurzen Impulszeiten eine gewebescheidigende Wärmeausbreitung in das umliegende Hautgewebe ausbleibt. Will man jedoch tieferliegende Strukturen, wie beispielsweise Haarwurzeln, über die kritische Temperatur von ca. 80°C erhitzen, ohne die oberen Hautschichten thermisch zu verletzen, so ist eine externe Kühlung unabdingbar, die die Absorptionswärme der Strahlung aus der obersten Hautschicht, die unverletzt bleiben soll, ableitet.

**[0005]** Aus der US-5,282,797 ist eine Bestrahlungseinrichtung bekannt, umfassend einen NIR-Laser, einen Lichtwellenleiter und einen mit einem Kühlmittel gefüllten Behälter. In einer bevorzugten Ausführungsform ist

der Behälter als flexibler Beutel mit einem Zulauf und einem Ablauf ausgebildet und in einen geschlossenen Kreislauf eingebunden. Der flexible Beutel wird zwischen der Haut und dem Lichtwellenleiter angeordnet. Durch die flexible Ausbildung des Beutels paßt sich dieser der Umgebung der Haut an, und der Lichtwellenleiter kann direkt auf den Beutel aufgesetzt werden. Beutel und Kühlmittel sind transparent für die NIR-Strahlung ausgewählt, so daß diese nahezu ungeschwächt auf die Haut auftrifft, wobei über das Kühlmittel der oberen Hautschicht Wärme entzogen wird und somit thermische Schädigungen der oberen Hautschicht vermieden werden. Nachteilig an den bekannten Bestrahlungsanordnungen mit NIR-Lasern sind die extrem großen Kosten. Ein weiteres Problem stellen die erforderlichen ultralangen NIR-Pulse mit einer Pulslänge von beispielsweise 50 - 200 ms mit einer Pulsenergie von beispielsweise 50 - 200 J dar, die nur mit großem Aufwand zu erreichen sind. Um in mehreren mm Tiefe noch ausreichende Energiedichten zu erreichen, wurde es erforderlich, die Behandlungsfläche auf mindestens 1 cm<sup>2</sup> und die Pulslängen auf bis zu mehrere 100 ms zu erhöhen.

**[0006]** Diese günstigen Behandlungsparameter kommen den physikalischen Eigenschaften eines Lasers nicht entgegen. Die Pulszeiten von gütegeschalteten Lasern sind so kurz, daß nur kleinste oberflächliche Strukturen behandelt werden könnten. Für verschiedene Hauterkrankungen ist die gleichzeitige Behandlung von einem oder mehreren cm<sup>2</sup> Hautoberfläche günstig. Die erforderliche Strahl-aufweitung von beispielsweise 40.000 µm<sup>2</sup> auf 1 cm<sup>2</sup> ist mit einem erheblichen technischen Aufwand verbunden und hebt gleichzeitig den eigentlichen lichtkonzentrierten Lasereffekt teilweise auf.

**[0007]** Der vergleichsweise schlechte Wirkungsgrad der Laser bedingt einen erhöhten technischen Aufwand, so daß in jüngster Zeit vermehrt Laserdiodenbarrn eingesetzt werden, bei denen eine Vielzahl einzelner Laserdioden von beispielsweise 1 - 3 W über Einzelfasern mit dem Einsatzort verkoppelt sind. Diodengepumpte Festkörperlaser, aber auch nichtkohärente Blitzlampen haben üblicherweise Pulslängen im ns- bis ms-Bereich, so daß aufwendige Resonatormodifikationen für längere Pulse notwendig sind. Laserdioden haben den Nachteil, daß diese aus thermischen Gründen nicht im gütegeschalteten Pulsbetrieb betrieben werden können, sondern sich lediglich im cw-Betrieb ein- und ausschalten lassen. Um die erforderliche Leistung zu erreichen, benötigt man eine sehr hohe Anzahl von Laserdiodenstacks, die zur Zeit mehrere 10.000 DM kosten.

**[0008]** Aus der US-5,620,478 ist eine Bestrahlungsanordnung mit einer nichtkohärenten Strahlungsquelle bekannt, die als Xenon-Hochdruckblitzlampe ausgebildet ist. Die Blitzlampe ist dabei in einem Reflektor angeordnet, dem ein Lichtwellenleiter zugeordnet ist, in den die erzeugte optische Strahlung eingekoppelt wird und

dessen Austrittsfläche auf die bestrahlte Hautpartie aufgesetzt wird. Aufgrund der divergenten Strahlung der Lichtquelle ist eine Kühleinrichtung, wie dies von den Laseranordnungen bekannt ist, nicht möglich, da es an den Grenzschichten zu dem Kühlmittel zu Reflexionen und Streuungen kommen würde. Daher wird als Alternative ein für die NIR-Strahlung transparentes, kühlendes Gel vorgeschlagen, das auf die zu behandelnde Hautpartie aufgetragen wird. Wie sich jedoch in der praktischen Anwendung gezeigt hat, ist die Wärmeabfuhr durch das Gel zu gering, so daß es häufig zu Verbrennungen in der oberen Hautschicht kommt. Ein weiterer Nachteil ist, daß infolge der hohen Plasmatemperatur von 6000°C ein bis in den UVC-Bereich reichendes kontinuierliches Spektrum mit nur einem geringen NIR-Anteil erzeugt wird, so daß der Wirkungsgrad verhältnismäßig schlecht ist. Zudem sind daher aufwendige Filtermaßnahmen zur Unterdrückung der nicht gewünschten Spektralbereiche notwendig. Weiterhin benötigen die Blitzlampen aufgrund der hohen Temperaturen eine aufwendige Wasserkühlung, die Service- und Herstellkosten weiter erhöhen.

**[0009]** Aus der US-5,344,418 ist eine Bestrahlungsanordnung mit einer Hochdruckentladungslampe als NIR-Lichtquelle bekannt, deren emittierte Strahlung in einem Lichtwellenleiter eingekoppelt wird, über eine erste Linse gesammelt, über einen Spiegel umgelenkt, eine zweite Linse gesammelt und über eine weitere aus Saphir bestehende Linse aus der Anordnung austritt. Die Saphirlinse wird dabei von einem Kühlgas wie CO<sub>2</sub>, Freon oder einem ähnlichen Gas umspült und entsprechend abgekühlt, wobei dann die gekühlte Saphirlinse direkt auf die zu behandelnde Hautpartie aufgesetzt wird. In einer alternativen Ausführungsform wird vorgeschlagen, daß das Licht aus dem Lichtwellenleiter direkt auf die Saphirlinse gestrahlt wird. Nachteilig an der bekannten Vorrichtung ist die geringe Wärmekapazität der Saphirlinse aufgrund des geringen Volumens. Verstärkt wird dieses Problem durch die Beschränkung auf Kühlgase, die im Vergleich zur Kühlflüssigkeit erheblich weniger Wärme aufnehmen können. Flüssigkeiten können wegen der ansonsten auftretenden Dispersion an der Saphirlinse nicht verwendet werden. Ein weiteres Problem stellen thermisch isolierende Dampfschichten des Kühlgases oberhalb der Saphirlinse dar, die durch geeignete Verwirbelungstechnik vermieden werden müssen.

**[0010]** Aus der US-5,830,208 ist eine Bestrahlungsanordnung bekannt, bei der die Kühleinrichtung als Peltierelement ausgebildet ist. Der eine Nachteil der bekannten Anordnung ist, daß die handelsüblichen Peltierelemente nicht ausreichend Kühlleistung zur Verfügung stellen, um Verbrennungen der oberen Hautschicht zu verhindern. Bei einem Einsatz der Peltierelemente in einer Anordnung gemäß der US-5,344,418 stellt sich zusätzlich das Problem, daß eine seitliche Kühlung der Saphirlinse aufgrund der geringen Umfangsfläche der Linse nur ungenügend ist. Verstärkt

wird dieser Effekt durch die notwendige seitliche Fassung der Linse, die wiederum einen erhöhten Wärmeübergangswiderstand bildet. Zudem führen geringe Luftspalte zwischen der Fassung und der Saphirlinse zu einer bereits erheblich ins Gewicht fallenden thermischen Isolierung der Saphirlinse.

**[0011]** Aus der US-5,814,040 ist eine Bestrahlungsanordnung mit einem NIR-Laser bekannt, der eine Sprüheinrichtung für ein Kältemittel, vorzugsweise R 134 A zugeordnet ist, mittels derer die zu behandelnde Hautoberfläche kurzzeitig im Bereich von 10 ms besprüht und somit gekühlt wird. Dadurch sollen einerseits die erwähnten Verbrennungen in der oberen Hautschicht vermieden werden und andererseits sichergestellt werden, daß die tieferliegenden, zu erwärmenden Hautschichten nicht abgekühlt werden. Zwar führt die entstehende Verdunstungswärme zu einem schnellen Abkühlen des Gewebes, jedoch ist die Abkühlung nur schwer steuerbar, so daß zum einen nur sehr kurze Impulse im Bereich von 100 ms verwendet werden und zum anderen durch starkes Anblasen vermieden werden muß, daß sich eine thermisch isolierende Kühlmittelschicht ausbildet. Unter ökologischen Gesichtspunkten ist weiterhin das Entweichen von für den Abbau der Ozonschicht verantwortlichen FCKW's bedenklich. Ein weiteres Problem stellt bei Verwendung nichtkohärenter Strahlungsquellen die Unterbrechung des Strahlenganges dar. Zwischen Haut und Applikatorende muß ein Luftspalt verbleiben, der für die Zufuhr von Kühlmittel benötigt wird. Dadurch entstehen jedoch zusätzliche Grenzschichten, die bei inkohärenten Strahlungsquellen zu erheblichen Einkoppelungsverlusten führen.

**[0012]** Aus der US-4,233,493 ist eine Bestrahlungsanordnung zum Stoppen von Blutungen bei chirurgischen Eingriffen bekannt, umfassend eine als Glühlampe ausgebildete NIR-Lichtquelle, einen die IR-Lichtquelle umgebenden Reflektor, einen Lichtwellenleiter und eine an der Austrittsöffnung des Lichtwellenleiters angeordnete Kappe oder Scheibe, die beispielsweise aus Quarz oder Saphir besteht. Die Glühlampe ist dabei vorzugsweise als konventionelle Wolfram-Glühlampe ausgebildet.

**[0013]** Der Erfindung liegt daher das technische Problem zugrunde, eine Bestrahlungsanordnung zur optischen Thermolyse zu schaffen, mit der unter Einsatz einer inkohärenten NIR-Lichtquelle eine ausreichende Kühlleistung zur Verhinderung von Verbrennungen in den oberen Hautschichten verfügbar ist. Ein weiteres technisches Problem ist die Schaffung einer preiswerten und kompakten pulsaren NIR-Lichtquelle.

**[0014]** Die Lösung des technischen Problems ergibt sich durch die Merkmale der Patentansprüche 1, 6 und 7. Weitere vorteilhafte Ausgestaltungen der Erfindung ergeben sich aus den Unteransprüchen.

**[0015]** Durch die einstückige Ausbildung des Lichtwellenleiters aus einem massiven Quarz oder Saphir,



dessen Umfang mindestens teilweise von einem in einem geschlossenen Kühlkreislauf befindlichen Kühlmittel umströmt wird, stellt der Lichtwellenleiter selbst eine große Wärmesenke dar, so daß es beim direkten Aufsetzen des Lichtwellenleiters auf die Hautoberfläche zu keinen Verbrennungen kommt, da die Absorptionswärme der oberen Hautschichten über eine direkte Wärmeleitung abgeführt wird. Ein weiterer Vorteil der Anordnung ist, daß durch die seitliche Kühlung sich kein Kühlmittel im Strahlengang der NIR-Lichtquelle befindet. Ein weiterer Vorteil der Anordnung ist, daß der Lichtwellenleiter auch in der Lage ist, rückgestreute Wärmestrahlung bis zu einer Wellenlänge von 5µm wieder einzukoppeln und abzuführen.

**[0016]** Vorzugsweise wird als Kühlmittel eine Kühlflüssigkeit verwendet, da diese erheblich mehr Wärme im Vergleich zu gasförmigen Kühlmitteln abführen können. Prinzipiell können alle bekannten Kühlflüssigkeiten verwendet werden, wie beispielsweise Wasser, Alkohol oder Glykol. Der Brechzahlunterschied zwischen Saphir bzw. Quarz zu den verwendeten Kühlmitteln ist dabei derart groß, daß fast eine vollständige Totalreflexion im Lichtwellenleiter auftritt. Der Strahlungsweg wird ähnlich wie bei einer kleinen Lichtleitfaser bis zum Ort des des Hautkontaktes nicht unterbrochen, so daß am Austrittsort gut durchmischtes Licht mit einer Apertur aus dem Verhältnis der beiden Brechzahlen austritt.

**[0017]** In einer weiteren bevorzugten Ausführungsform ist der Lichtwellenleiter zylinderförmig oder rechteckförmig ausgebildet. Die zylinderförmige Ausführungsform läßt sich sehr einfach herstellen und mittels O-Ringen abdichten, wobei der Durchmesser des Zylinders beispielsweise 12mm bei einer Länge von 70 mm beträgt. Der Vorteil einer rechteckförmigen Ausbildung von beispielsweise 8mm X 35mm ist, daß längere Gefäße simultan in ihrem Gesamtverlauf erwärmbar sind, so daß eine Wirkungsverminderung durch die Eigenkühlung des Gefäßes reduziert wird.

**[0018]** In einer weiteren bevorzugten Ausführungsform wird das langwellige Infrarot unterdrückt. Hierzu gibt es prinzipiell verschiedene Möglichkeiten. Im einfachsten Fall wird zwischen der NIR-Lichtquelle und der Stirnseite des Lichtwellenleiters ein entsprechender Filter angeordnet, der diesen Spektralbereich unterdrückt. Allerdings stellt die thermische Belastung der Filter ein Problem dar. Daher wird vorzugsweise der langwellige Infrarotfilter der das Applikatorende bildenden Stirnseite zugeordnet, wo dieser beispielsweise mittels eines geeigneten thermischen und optischen Kitts mit der Stirnseite verbunden wird.

**[0019]** In einer alternativen Ausführungsform wird ausgenutzt, daß die Kühlflüssigkeiten, insbesondere Wasser sehr gute langwellige IR-Filter darstellen. Insbesondere Wasser filtert exakt die Spektralbereiche heraus, die ansonsten zu einer unerwünschten Eiweißkoagulation an der Hautoberfläche führen könnten. Daher wird die der NIR-Lichtquelle zugeordnete Stirnseite vollständig innerhalb der Kühlflüssigkeit angeord-

net. Zwischen der NIR-Lichtquelle und der Stirnseite wird dann der Kühlkreislauf mittels eines Quarz- oder Saphirfensters verschlossen. Die zuvor erwähnten Probleme beim Durchgang inkohärenter Strahlung durch eine Flüssigkeitsschicht können durch eine entsprechend große Apertur der NIR-Lichtquelle gelöst werden, was später noch näher erläutert wird.

**[0020]** Eine weitere Möglichkeit zur Unterdrückung der langwelligen Infrarotstrahlung besteht darin, beispielsweise die NIR-Lichtquelle in einem Brennpunkt eines Ellipsoid-Reflektors anzuordnen, in dessen anderem Brennpunkt die Stirnseite des Lichtwellenleiters angeordnet ist. Der Reflektor besteht aus einem langwellige Infrarotstrahlung transmittierenden Material wie beispielsweise Teflon. Zur Verhinderung einer direkten Einkopplung von der NIR-Lichtquelle in den Lichtwellenleiter ist im direkten Strahlengang ein Filter oder ein weiterer Reflektor angeordnet. Der Vorteil dieser Anordnung ist, daß die NIR-Nutzstrahlung nicht eine Flüssigkeitsschicht passieren muß, jedoch verliert die Bestrahlungsanordnung aufgrund des Volumens des Ellipsoid-Reflektors etwas von seiner Kompaktheit.

**[0021]** Eine weitere bevorzugte Anwendung bezieht sich auf den Einsatz der Anordnung zu einer gewebeschonenden Kryotherapie. Üblicherweise wird die Kryotherapie mit einem Metallapplikator durchgeführt, der von innen entweder mit einem Kühlmittel, wie beispielsweise R 134 A, oder direkt mit flüssigem Stickstoff durchströmt wird. Setzt man einen derartig vorgekühlten Applikator auf die zu behandelnde Läsion, wie beispielsweise ein oberflächliches Karzinom, auf, so kommt es entsprechend der gewebetypischen Wärmeleitkonstante und dem Wärmeübergang zwischen Gewebe und Applikator zu einer Kälteausbreitung im Gewebe. Diese Kälteausbreitung erfolgt in annähernd konzentrischen Isothermen, wobei vor allem größere, schnell fließende Gefäße das isothermische Ausbreitungsprofil deformieren.

**[0022]** Der erfrierungsbedingte Gewebeschaden wird durch eisbedingte, biophysikalische Gewebeveränderungen verursacht. Insbesondere intrazelluläres Eis kommt über ein direktes Zerreißen von Zellmembranstrukturen eine besonders schädliche Rolle zu. Die Entstehung von physikalisch wirksamem, intrazellulärem Eis kann nun durch bestimmte Maßnahmen verhindert werden. Hierzu gehören die Induktion von Scherkräften mit Hilfe von Ultraschall, Magnetfeldern oder photoakustischen Verfahren. Darüber hinaus ist es mit Hilfe einer gepulsten, zeitlich synchronisierten Bestrahlung der zu schützenden Hautoberfläche möglich, den Grad des "undercooling" erheblich anzuheben. Hierunter versteht man die Absenkung der Temperatur unterhalb des Schmelzpunktes, wobei durch Abwesenheit von Kristallisationskeimen die gewebeschädigende Eisbildung erheblich verhindert werden kann.

**[0023]** Mit der Anordnung ist es somit möglich, tiefere Gewebsstrukturen einer Kryotherapie zu unterziehen und gleichzeitig durch eine Beeinflussung der

oberen Gewebeschichten mit Hilfe von optischer, magnetischer und akustischer Energie deren Schädigung zu verhindern. Die bevorzugte Anwendung erlaubt nun erstmals auch die kryotherapeutische Behandlung von tieferen Gewebsstrukturen, wie beispielsweise Haarwurzeln oder Gefäßanomalien. Ein weiterer möglicher Vorteil der Kryotherapie ist ihre gewebschonende Anwendung.

**[0024]** Im Gegensatz zu einer Kryotherapie kommt es bei einer Photokoagulation immer zu einer Proteindenaturierung. Dies löst in der Regel immer eine starke Entzündungsreaktion aus, in dessen Rahmen die beteiligten Entzündungszellen sekundäre Schäden verursachen. Hierzu gehören beispielsweise Narben und Hyperpigmentierungen. Wird die erwünschte Gewebekrose nicht durch Hitzeeinwirkung sondern durch Kälteeinwirkung erzeugt, so ist die hierbei auftretende Nekrose mit einer wesentlich kleineren Entzündungsreaktion verbunden, da es zwar durch Mikrokristallbildung in den Einzelzellen zu einer Perforation der Zellwand, einen Austritt von Intrazellulärlüssigkeit und nachfolgendem Zelltod kommt, jedoch treten in diesem Fall zu keiner Zeit denaturierte Eiweiße auf. Kryotherapie wurde bisher ausschließlich mit Hilfe von Applikatoren durchgeführt, die eine Schonung der oberen Gewebsschichten nicht zulassen.

**[0025]** Die Bestrahlungsanordnung kann neben der bereits erwähnten optischen Thermolyse auch zur Behandlung von Hämorrhoiden, der lokalisierten Form der Schuppenflechte (Plaques), NIR-Bindegewebsinteraktion (Zellulite) sowie einiger Formen des Prostatahypertrophie-Symptomenkomplexes verwendet werden. Bei einer Senkung der Bestrahlungsstärke kann die Bestrahlungsanordnung bei chronisch rezidivierenden Entzündungen im Nasennebenhöhlen- und Stirnhöhlenbereich eingesetzt werden, wo der schleimlösende Einfluß derartiger Wärmebehandlungen ausgenutzt wird. Ein weiteres Anwendungsfeld ist die günstige Beeinflussung von kollagensynthetisierenden Fibroblasten, bei denen durch NIR eine Änderung des Kollagensyntesemusters erreicht werden kann. Hiermit ist sowohl eine positive Beeinflussung von alterungsbedingten Hautfalten als auch der bindegewebsbedingten ungleichmäßigen Fettzellenanordnung (Zellulite) möglich.

**[0026]** In einer weiteren bevorzugten Ausführungsform umfaßt die NIR-Lichtquelle eine Wolfram-Nacktwendel, einen halboffenen Reflektor, eine Schutzgasquelle und eine Spannungspulse erzeugende Spannungsquelle, wobei die Wolfram-Nacktwendel einseitig im Reflektor gesockelt und mit der Spannungsquelle verbunden ist, der Lichtwellenleiter in den halboffenen Reflektor hineinragt, so daß zwischen Lichtwellenleiter und Reflektor eine Öffnung definiert wird, über die Schutzgas in den Reflektor ein- und/oder ableitbar ist. Vorzugsweise ist der Reflektor als Keramikreflektor ausgebildet und derart dimensioniert, daß dieser direkt auf den Lichtwellenleiter aufgesetzt wer-

den kann. Hierbei kommt es nicht zu einem luftdichten Abschluß, sondern es verbleibt entweder ein umlaufender Randspalt, oder es wird über eine oder mehrere kleine Kerben eine Undichtigkeit erzeugt. Über eine externe Zuleitung, beispielsweise eine feine Bohrung in der Nähe des Wendelsockels, wird dann das Schutzgas eingeleitet und kann über die Öffnungen zwischen Lichtwellenleiter und Reflektor entweichen. Dadurch entsteht eine äußerst kompakte Anordnung, bei der der Abstand zwischen der emittierenden Wolfram-Nacktwendel und dem Lichtwellenleiter sehr gering ist, so daß die Einkoppelverluste ebenfalls sehr gering sind. Des weiteren erlaubt diese Anordnung ein einfaches Auswechseln von defekten Wendeln, sowie den problemlosen Einsatz verschiedener Wendelgeometrien, wobei vorzugsweise Flachwendeln zur Anwendung kommen. Ein weiterer Vorteil dieser Anordnung ist, daß diese vollkommen drucklos aufgebaut ist, so daß keinerlei Explosionsgefahr besteht. Im Falle eines Versagens der Schutzgaszufuhr verglüht lediglich die Wendel in wenigen Millisekunden, und das Gerät stellt seine Funktion ein. Im Gegensatz zu gepulsten Gasentladungslampen entfallen bei dieser Anordnung Hochspannungsbauteile. Bei Verwendung von Nieder-voltwendeln und der Bereitstellung entsprechender dimensionierter Kupferzuleitungen kann die Lichtquelle beispielsweise mit 48 V gepulst werden, wodurch die Patientensicherheit weiter erhöht wird. Ein weiterer Vorteil des Schutzgasstromes ist, daß die Glühwendel stärker im Überlastbereich betrieben werden kann, ohne daß es zu einem Aufschmelzen kommt, da der Schutzgasstrom als Kühlmittel für die Wendel wirkt. Des weiteren ist es möglich, die Oberfläche der Glühwendel mit einer geeigneten Mikrostrukturierung auszubilden, um durch Interferenzeffekte das abgestrahlte Spektrum zu beeinflussen. Da die Strukturierung von Mehrfachwendeln relativ aufwendig ist, kann daher in einer weiteren bevorzugten Ausführungsform eine Wolframfolie verwendet werden, wie sie aus Bandlampen bekannt ist. Diese Wolframfolie kann dann beispielsweise durch chemische Bedampfungsverfahren oder Ionenätzung mikrostrukturiert werden.

**[0027]** Alternativ kann die pulsable NIR-Lichtquelle durch eine Glühwendel-Halogenlampe realisiert werden, die beispielsweise von einer Kondensatorbatterie mit einem rechteckförmigen Überspannungspuls von beispielsweise 500 V über 20 - 200 ms betrieben wird. Trotz der extremen Stromstärken von mehreren 10 A kommt es nicht zu einem Durchglühen der Wendel, sondern zu einer überraschend extremen Verkürzung der Anstiegszeit in eine Größenordnung von 7 ms (Vergleich: Wird eine handelsübliche Glühwendel-Halogenlampe ans Netz geschaltet, so ist die Anstiegszeit ungefähr 200 - 300 ms). Durch die extreme Kurzzeitüberlastung kommt es darüber hinaus zu einer Erhöhung der Wendeltemperatur auf über 3000°C und hiermit zu einer Verschiebung des Strahlungsmaximums zu kleineren Wellenlängen. Bei einer bevorzug-

ten Ausführung der Glühwendel aus Wolfram verschiebt sich das Maximum von 1000 nm auf 870 nm. Neben einer besseren Ausnutzung des sogenannten optischen Fensters der Haut, ist auch die Flächenleistung der Glühwendel in Folge ihrer höheren Temperatur und der damit verbundene Wirkungsgrad signifikant erhöht. Ein weiterer Vorteil dieser Betriebsart bezieht sich auf die Beeinflussung der Wolframwendelstruktur selbst. Im Herstellungsprozeß wird ein fibröses Drahtmaterial verwendet, das eine ausreichende Duktilität für die Biegun-  
 5 gsvorgänge besitzt. Für einen befriedigenden Lampenbetrieb ist die Umsetzung in eine kristalline Struktur günstig. Beispielsweise wird in der US-4,012,659 und der US-4,020,383 beschrieben, daß elektrische Pulse die Lebensdauer von normalen Glühlampen günstig beeinflussen. Neben der Wolframrekristallisierung wird erwähnt, daß mit Hilfe der Pulse Kontaktprobleme, beispielsweise aufgrund von Oxidation, zwischen der Drahtaufhängung und der Wolframwendel beseitigt werden können.

**[0028]** Eine weitere Möglichkeit, die Abstrahlleistung weiter zu erhöhen, ist eine möglichst enge Ummantelung der Halogenlampe durch einen Reflektor, der lediglich im Auskoppelbereich geöffnet ist, wobei der Reflektor beispielsweise als polierter Metallreflektor ausgebildet ist. Hierdurch kommt es zu einer Reabsorption der reflektierten Strahlung durch die Wendel und damit zu einer weiteren Erhöhung des Wirkungsgrades im Nutzstrahlbereich.

**[0029]** Die Erfindung wird nachfolgend anhand eines bevorzugten Ausführungsbeispiels näher erläutert. Die Fig. zeigen:

- Fig.1 eine Prinzipdarstellung einer Bestrahlungsanordnung zur optischen Thermolyse,
- Fig.2 einen Längsschnitt durch den Lichtwellenleiter,
- Fig.3 eine Prinzipdarstellung der Bestrahlungsanordnung mit unterdrückter langwelliger Infrarotstrahlung und
- Fig.4 eine Prinzipdarstellung einer Bestrahlungsanordnung für die Kryotherapie.

**[0030]** Die Bestrahlungsanordnung 1 zur optischen Thermolyse umfaßt eine pulsare NIR-Lichtquelle 2, einen Lichtwellenleiter 3 und eine Kühleinrichtung 4. Die Kühleinrichtung 4 umfaßt neben einem Sammelgefäß für die Kühlflüssigkeit 9 einen Zulauf 5, einen Abfluß 6 und einen zylinderschalenförmigen Bereich 7, der den Lichtwellenleiter 3 nahezu vollständig umgibt. Der zylinderschalenförmige Bereich 7 ist mittels O-Ringen 8 hermetisch dicht um den Lichtwellenleiter 3 herum angeordnet, so daß sich ein geschlossener Kühlkreislauf ergibt. Der Lichtwellenleiter 3 ist als massiver Zylinder aus Saphir oder Quarz ausgebildet, dessen der NIR-Lichtquelle 2 zugewandte Stirnfläche 10 möglichst dicht der NIR-Lichtquelle 2 zugeordnet ist. Die gegenüberliegende Stirnseite 11 bildet das Applikatorende,

das direkt auf einen zu behandelnden Hautbereich 12 aufgesetzt wird. Die NIR-Lichtquelle 2 ist als Glühwendel-Halogenlampe mit einer Glühwendel 13 aus Wolfram ausgebildet, die mittels einer nicht dargestellten Spannungsquelle im Überlastbereich angesteuert wird. Um den Quarzkolben der Glühwendel-Halogenlampe ist ein Reflektor angeordnet, der nur im Bereich der Stirnfläche 10 des Lichtwellenleiters 3 offen ist. Die von der NIR-Lichtquelle 2 emittierte NIR-Strahlung wird in die Stirnseite 10 eingekoppelt und tritt an der Stirnseite 11 aus. Die austretende NIR-Strahlung dringt dann in die Haut 12 ein und wird von den Gefäßen absorbiert. Der fast vollständig von Kühlflüssigkeit 9 umströmte Lichtwellenleiter 3 stellt dann eine sehr große Wärmesenke für die oberste Hautschicht dar und verhindert so Verbrennungen aufgrund zu großer Wärmeentwicklung. Somit übernimmt der Lichtwellenleiter 3 in der Bestrahlungsanordnung 1 eine Doppelfunktion, nämlich die des optischen Leiters und die eines Kühlelementes. Daher muß das Material sowohl ausreichend gute optische als auch thermische Eigenschaften hinsichtlich der Wärmeleitfähigkeit aufweisen. Diese beiden Eigenschaften werden sehr gut von Saphir, Quarz und Diamant erfüllt, wobei letzterer zwar physikalisch am geeignetsten ist, jedoch auch am teuersten ist, so daß zumindest derzeit aus kostentechnischen Gründen eine Verwendung nicht in Frage kommt. Prinzipiell kämen aber Kunststoffe in Frage, die die beiden notwendigen physikalischen Eigenschaften miteinander vereinen.

**[0031]** In der Fig.2 ist der Lichtwellenleiter 3 im Längsschnitt dargestellt. Die NIR-Nutzstrahlung 14 bewegt sich mittels Totalreflexion im Lichtwellenleiter 3 fort, wenn der Aufttrittswinkel an der Grenzfläche zur Kühlflüssigkeit 9 größer als ein Grenzwinkel ist. Dieser von den Brechzahlen abhängige Grenzwinkel liegt für Saphir und die üblichen Kühlflüssigkeiten bei ca. 30°, so daß die Ausbreitungsverluste äußerst gering sind. Aufgrund des Temperaturgradienten an der Haut 12 kommt es zu einem direkten Wärmestrom 15 von der Haut 12 zum Lichtwellenleiter 3, wo die Wärme über die Kühlflüssigkeit 9 abgeführt wird. Des weiteren wird von der Haut 12 reflektierte Wärmestrahlung 16 in die Stirnseite 11 des Lichtwellenleiters 3 eingekoppelt und ebenfalls abgeführt.

**[0032]** In der Fig.3 ist eine Bestrahlungsanordnung 1 mit Unterdrückung langwelliger Infrarotstrahlung dargestellt. Der wesentliche Unterschied zur Bestrahlungsanordnung 1 gemäß Fig.1 besteht darin, daß die der NIR-Lichtquelle 2 zugeordnete Stirnseite 10 des Lichtwellenleiters 3 sich vollständig innerhalb der Kühlflüssigkeit 9 befindet. Zwischen der NIR-Lichtquelle 2 und der Stirnseite 10 ist der Kühlkreislauf mittels eines Quarz- oder Saphirfensters 17 abgeschlossen. Die Apertur der NIR-Lichtquelle 2 und des Quarz- oder Saphirfensters 17 ist dabei wesentlich größer als die der Stirnseite 10 des Lichtwellenleiters 3. Bei diesem Aufbau sind folgende Vorüberlegungen von Interesse.

**[0033]** Jeder Lichtwellenleiter 3 oder jede Lichtleit-

faser weist einen Öffnungswinkel auf. Strahlung, die innerhalb dieses Winkels auf den Lichtwellenleiter trifft, wird eingekoppelt und mittels Totalreflexion weitergeleitet. Strahlung außerhalb dieses Winkels geht durch Reflexion beim Einkoppeln bzw. als Transmissionsverlust im Lichtwellenleiter verloren. Der Öffnungswinkel ist abhängig von der Differenz der Brechungsindices. Bei Luft als Umgebung gilt:

$$\sin i = (n_{\text{Kern}}^2 - n_{\text{Mantel}}^2)^{1/2},$$

wobei  $i$  der Akzeptanzwinkel der Faser ist. Befindet sich der Lichtwellenleiter 3 ohne separaten Mantel an der Luft, so ist der Akzeptanzwinkel  $90^\circ$  für alle Materialien mit einem Brechungsindex größer  $2^{1/2}$ , so daß die gesamte Strahlung aus dem Halbraum in die Faser eingekoppelt und weitergeleitet wird. Da der Brechungsindex von Saphir 1,77 beträgt, existiert ein Akzeptanzwinkel von  $90^\circ$  für alle Mantelmaterialien mit einem Brechungsindex kleiner 1,46 (z.B. Wasser). Aufgrund der winkelabhängigen Reflexion treten erhebliche Reflexionsverluste bei Einfallswinkeln größer  $70^\circ$  auf. Aufgrund dieser Tatsache können die Einkoppel-Verluste durch den Durchgang durch die wasserhaltige Kühlflüssigkeit 9 durch eine entsprechend vergrößerte Apertur der Glühwendel 13 bzw. der Bandwendel kompensiert werden.

**[0034]** Das Quarzfenster 17 ist beispielsweise 2 mm dick und der Abstand zwischen der Innenseite des Quarzfensters 17 zur Stirnfläche 10 des Lichtwellenleiters 3 ca. 4 mm. Daraus ergibt sich bei einem Durchmesser des Lichtwellenleiters 3 von 13 mm ein optimaler Durchmesser der NIR-Lichtquelle 2 von 24 mm. Die Ausbildung des Fensters 17 aus Quarz hat gegenüber Saphir neben dem Vorteil der geringeren Kosten den weiteren Vorteil, daß das Quarz bereits einen Teil des langwelligen infrarotlichtes absorbiert. Die restliche langwellige infrarotstrahlung wird dann von der Kühlflüssigkeit 9 absorbiert. Zur Unterdrückung möglicher Anteile der Nutzstrahlung im sichtbaren Bereich können diese durch geeignete Farbstoffe in der Kühlflüssigkeit herausgefiltert werden.

**[0035]** In einer alternativen Ausführungsform wird das Quarzfenster 17 und die darunterliegende Flüssigkeitsschicht durch einen Konus aus optisch transparentem Material ersetzt. Als Material kommen insbesondere Quarz oder BK7-Glas in Frage. Die Stirnflächen des Konus sind vorzugsweise plangeschliffen und poliert. Der lampennahe Durchmesser der ersten Stirnfläche beträgt beispielsweise 30 mm, wohingegen der lampenferne Durchmesser ca. 12 mm beträgt. Der Konuswinkel liegt dabei zwischen  $10-15^\circ$ . Vorzugsweise ist der gesamte Konus von einem infrarotreflektierendem Trichter umgeben, der vorzugsweise durch eine Goldschicht gebildet wird. Zwischen Trichter und Konus bleibt ein Randspalt erhalten, um einerseits die Totalreflexion zwischen Konusmaterial und Luft auszunutzen. Andererseits wirft der vergoldete Trichter Lichtstrahlen

zurück in das optische System, die den Grenzwinkel für die Totalreflexion überschritten hatten. Die optische Kopplung zwischen der lampenfernen Stirnfläche des Konus und des Lichtwellenleiters 3 erfolgt vorzugsweise durch Silikonöl im Kapillarspalt beider Stirnflächen. Der Lichtwellenleiter 3 ist vorzugsweise als Saphirstab ausgebildet und wird teilweise im Mantelbereich durch eine Flüssigkeitsperfusion gekühlt. In Abhängigkeit von der Infrarotabsorption des Perfusionskühlmittels kann es vorteilhaft sein, den Saphirzylinder im Bereich des Flüssigkeitsmantels zu vergolden, da der Flüssigkeitsmantel im Vergleich zu einem Luftmantel den Grenzwinkel für die Totalreflexion absenkt. Alternativ zur Goldschicht auf dem Saphirzylinder kann dieser auch in einer Hülse aus IR-reflektivem Material geführt werden. Patienten-seitig ragt der Sapir ca. 2 bis 3 cm aus der Fassung, um eine möglichst hohe optische Transparenz der Behandlungsfläche zu gewährleisten. Die mittel- und langwellige IR-Absorption wird entweder durch den Werkstoff des Konus, wie beispielsweise BK7-Glas, oder mittels Filtern erreicht, wobei die Filter vorzugsweise zwischen Konus und Saphirzylinder angeordnet werden.

**[0036]** In der Fig.4 ist eine Bestrahlungsanordnung 1 für die Kryotherapie dargestellt, die in ihrem Aufbau der Bestrahlungsanordnung 1 gemäß Fig. 3 entspricht. Zusätzlich weist die Bestrahlungsanordnung 1 einen piezokeramischen Ultraschalltransducer 18 auf, der eine ungewollte Eiskristallbildung verhindern soll. Diese Betriebsart unterscheidet sich von der vorher genannten optischen Thermolyse dadurch, daß die erwünschten Gewebseinwirkungen, wie beispielsweise Thrombosierung von Krampfaden, nicht in einer Wärmezufuhr sondern in einem Wärmeentzug bestehen. Deshalb ist es erforderlich, die Temperatur des Kühlmittelapplikators so weit wie möglich zu senken, wozu als Kühlflüssigkeit 9 vorzugsweise flüssiger Stickstoff verwendet wird. Die optische Energie der NIR-Lichtquelle 2 wird in diesem Fall lediglich für die Erwärmung der obersten Hautschichten verwendet. Die hierfür erforderliche Energie von beispielsweise 5 - 20 J ist wesentlich geringer als für die direkte Photoakagulation von beispielsweise 100 - 300 J. In Abhängigkeit von der gewebstypischen Anzahl an Kristallkeimpunkten sowie deren Wachstumsverhalten ist es sinnvoll, eine hierauf abgestimmte gepulste Bestrahlung durchzuführen. Hierdurch wird in den oberen Gewebsschichten ein zyklischer Temperaturverlauf erzeugt, der die Entstehung von intrazellulärem Eis verhindert. Hierdurch kann die Temperatur zum Teil weit unter den Schmelzpunkt der Gewebeflüssigkeit abgesenkt werden, ohne daß es zu einer Eisbildung im Gewebe kommt. Die durch den Ultraschall-Transducer 18 erzeugte Ultraschallenergie verursacht darüber hinaus Scherkräfte, die der Eisbildung zusätzlich entgegenwirken.

**[0037]** Das Gewebe wird in diesem sogenannten Zustand des "supercooling" in keiner Weise geschädigt, da lediglich alle biochemischen Prozesse reversibel

stark verlangsamt werden, ohne daß es zu einem mechanischen Zell- oder Gewebeschaden kommt. Für die Gefrierwirkung auf das tieferliegende Gewebe ist der mittlere Temperaturgradient der Gewebeoberfläche zum tieferen Gewebe entscheidend. Da Temperaturen von unterhalb ca. -40°C ausreichen, irreversible Gewebeschäden zu erzeugen, muß die Temperatur des Kühlmittelapplikators so tief gewählt werden, daß unter Berücksichtigung des zu erreichenden supercooling-Zustandes bzw. der zyklischen Temperaturanhebung in Gefrierpunktsnähe immer noch ein ausreichender Kältgradient vorhanden bleibt. Ein direkt mit flüssigem Stickstoff gefüllter Saphirapplikator, durch dessen Querschnitt eingestrahlte optische Energie die oberen Hautschichten bis auf 0°C kurzzeitig erwärmt, verursacht einen effektiven Temperaturgradienten von beispielsweise ca. -80 °C. Diese Temperatur ist mehr als ausreichend, um eine ausreichend schnelle Gefrierzonenausbreitung in den gewünschten Arealen zu erreichen.

#### Patentansprüche

1. Bestrahlungsanordnung, insbesondere zur optischen Thermolyse, umfassend eine nichtkohärente NIR-Lichtquelle, einen der NIR-Lichtquelle zugeordneten Lichtwellenleiter und eine Kühleinrichtung, **dadurch gekennzeichnet, daß** der Lichtwellenleiter (3) einstückig aus einem massiven Saphir oder Quarz gebildet ist, um dessen Umfang mindestens teilweise ein in einem geschlossenen Kühlkreislauf befindliches Kühlmittel sich befindet.
2. Bestrahlungsanordnung nach Anspruch 1, dadurch gekennzeichnet, daß das Kühlmittel als Kühlflüssigkeit (9) ausgebildet ist.
3. Bestrahlungsanordnung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Lichtwellenleiter (3) zylinder- oder quaderförmig ausgebildet ist.
4. Bestrahlungsanordnung nach einem der vorangegangenen Ansprüche, dadurch gekennzeichnet, daß der Stirnseite (11) des Lichtwellenleiters (3) ein langwelliger Infrarotfilter zugeordnet ist.
5. Bestrahlungsanordnung nach einem der Ansprüche 2 oder 3, dadurch gekennzeichnet, daß die Stirnseite (10) des Lichtwellenleiters (3) innerhalb der Kühlflüssigkeit (9) angeordnet ist und der Kühlkreislauf im Bereich zwischen der NIR-Lichtquelle (2) und der Stirnseite (10) des Lichtwellenleiters (3) mittels eines Quarz- oder Saphirfensters geschlossen ist.
6. Bestrahlungsanordnung nach einem der Ansprüche 2 bis 4, dadurch gekennzeichnet, daß zwischen der NIR-Lichtquelle (2) und dem Lichtwellenleiter (3) ein Konus aus optisch transparentem Material angeordnet ist, dessen kleinerer Durchmesser dem Lichtwellenleiter (3) zugeordnet ist.
7. Bestrahlungsanordnung nach Anspruch 6, dadurch gekennzeichnet, daß der Konus aus Quarz oder BK7-Glas besteht.
8. Bestrahlungsanordnung nach Anspruch 6 oder 7, dadurch gekennzeichnet, daß um den Konus ein infrarotreflektierender Trichter angeordnet ist.
9. Bestrahlungsanordnung nach einem der Ansprüche 2 bis 8, dadurch gekennzeichnet, daß der Lichtwellenleiter im Bereich der Flüssigkeitskühlung mit einer infrarotreflektierenden Schicht beschichtet oder in einer infrarotreflektierenden Hülse geführt ist.
10. Pulsbare NIR-Lichtquelle zur Erzeugung von Pulslängen größer 20ms, insbesondere zur Verwendung in einer Bestrahlungsanordnung nach einem der vorangegangenen Ansprüche, dadurch gekennzeichnet, daß die NIR-Lichtquelle (2) eine Wolfram-Nacktwendel, einen halboffenen Reflektor, einen Lichtwellenleiter (3), eine Schutzgasquelle und eine Spannungspulse erzeugende Spannungsquelle umfaßt, wobei die Wolfram-Nacktwendel einseitig im Reflektor gesockelt und mit der Spannungsquelle verbunden ist, der Lichtwellenleiter (3) in den halboffenen Reflektor hineinragt, so daß zwischen Lichtwellenleiter (3) und Reflektor eine Öffnung definiert wird, über die Schutzgas in den Reflektor ein- und/oder ableitbar ist.
11. Pulsbare NIR-Lichtquelle zur Erzeugung von Pulslängen größer 20ms, insbesondere zur Verwendung in einer Bestrahlungsanordnung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die NIR-Lichtquelle (2) als Glühwendel-Halogenlampe ausgebildet ist, der eine Spannungspulse erzeugende Spannungsquelle zugeordnet ist, wobei die Spannungspulse einen Überlastbetrieb der Glühwendel-Halogenlampe erzeugen.
12. Pulsbare NIR-Lichtquelle nach Anspruch 11, dadurch gekennzeichnet, daß die Glühwendel (13) aus Wolfram gebildet ist.
13. Pulsbare NIR-Lichtquelle nach Anspruch 11 oder 12, dadurch gekennzeichnet, daß um den Quarzhüllkörper der Glühwendel-Halogenlampe teilweise ein Reflektor angeordnet ist.

14. Pulsbare NIR-Lichtquelle nach einem der Ansprüche 10 bis 13, dadurch gekennzeichnet, daß die strahlende Fläche durch chemische und/oder physikalische Verfahren mikrostrukturiert ist, so daß unerwünschte Wellenlängen interferenzoptisch ausgelöscht werden. 5

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Fig. 1

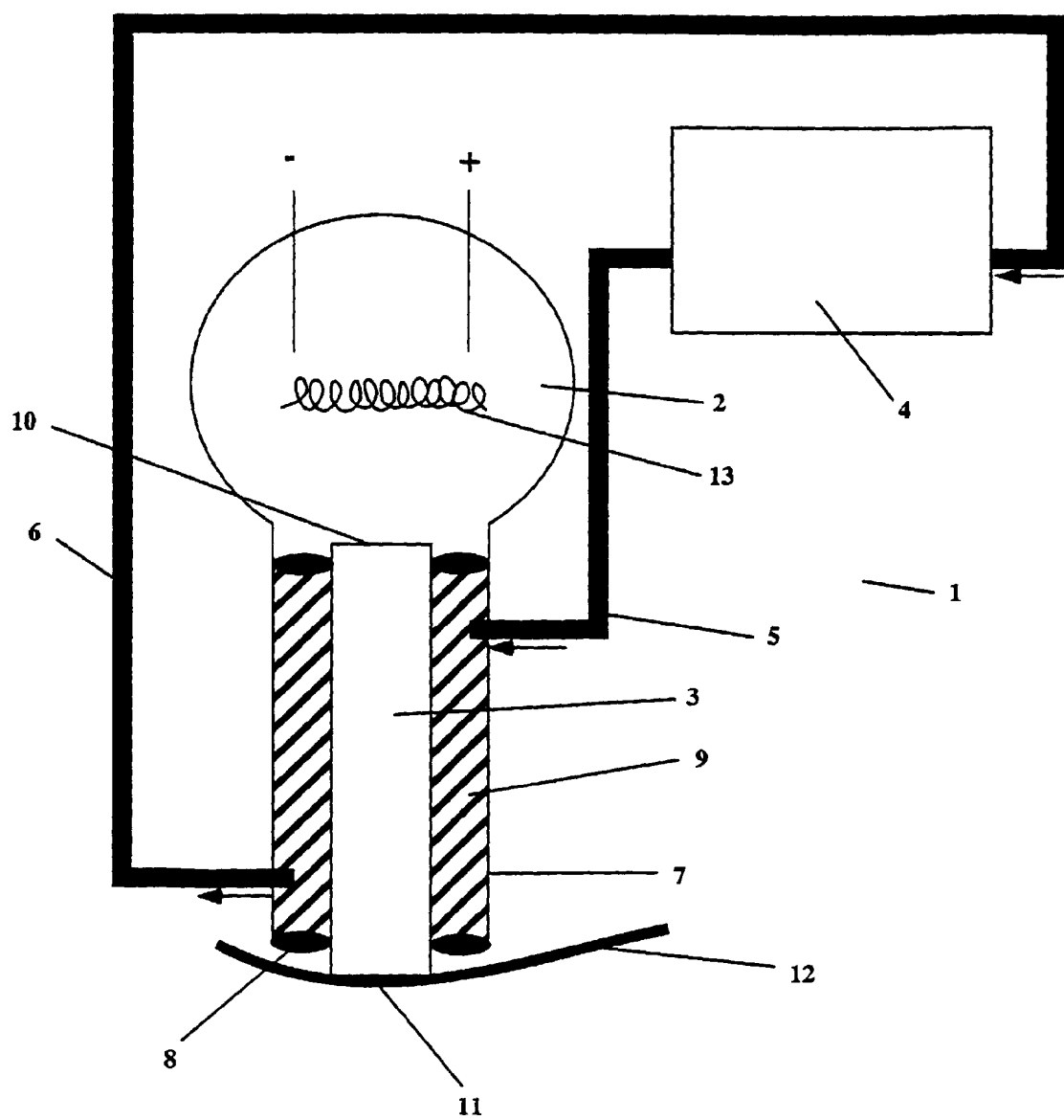


Fig.2

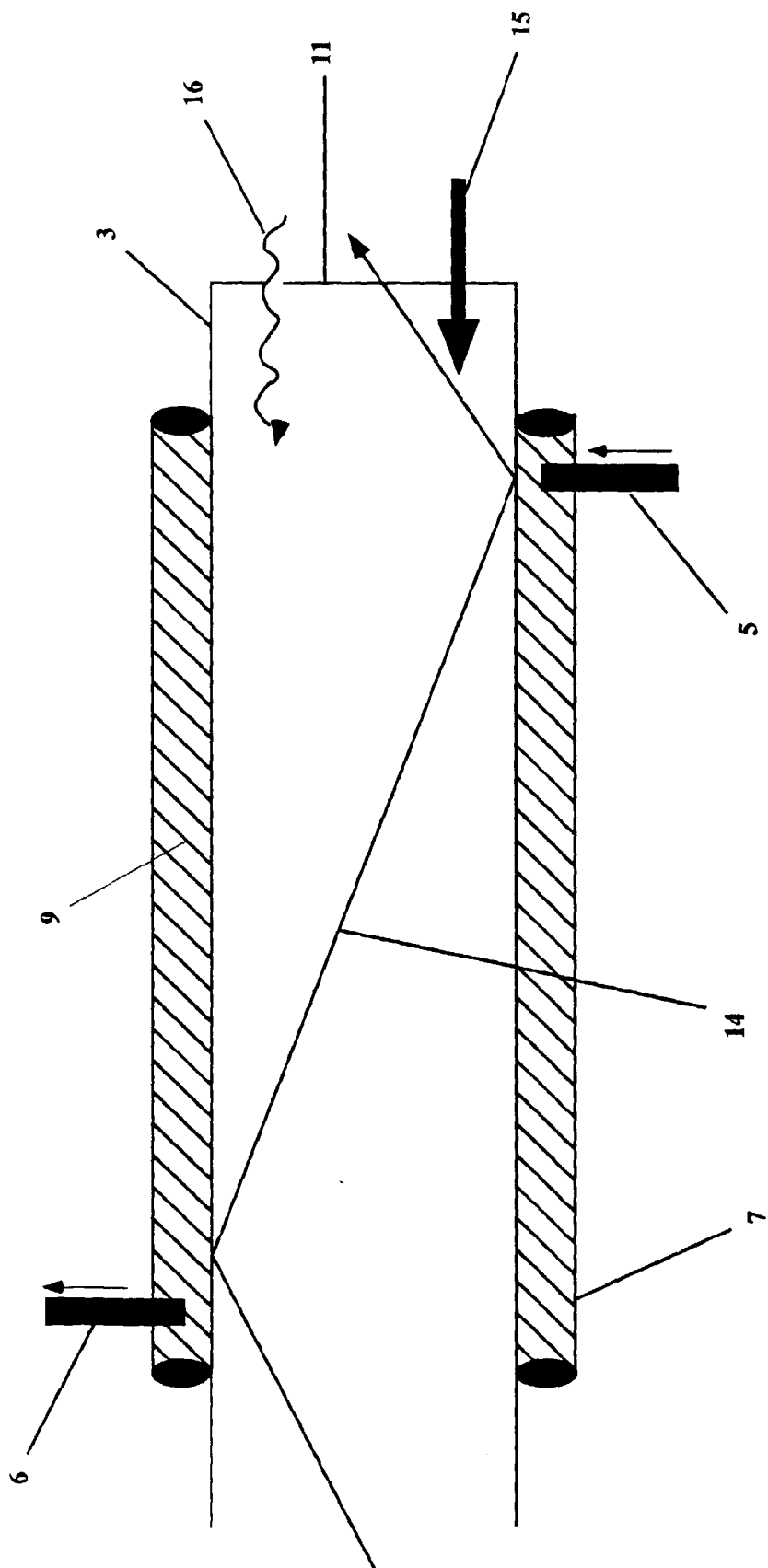




Fig.3

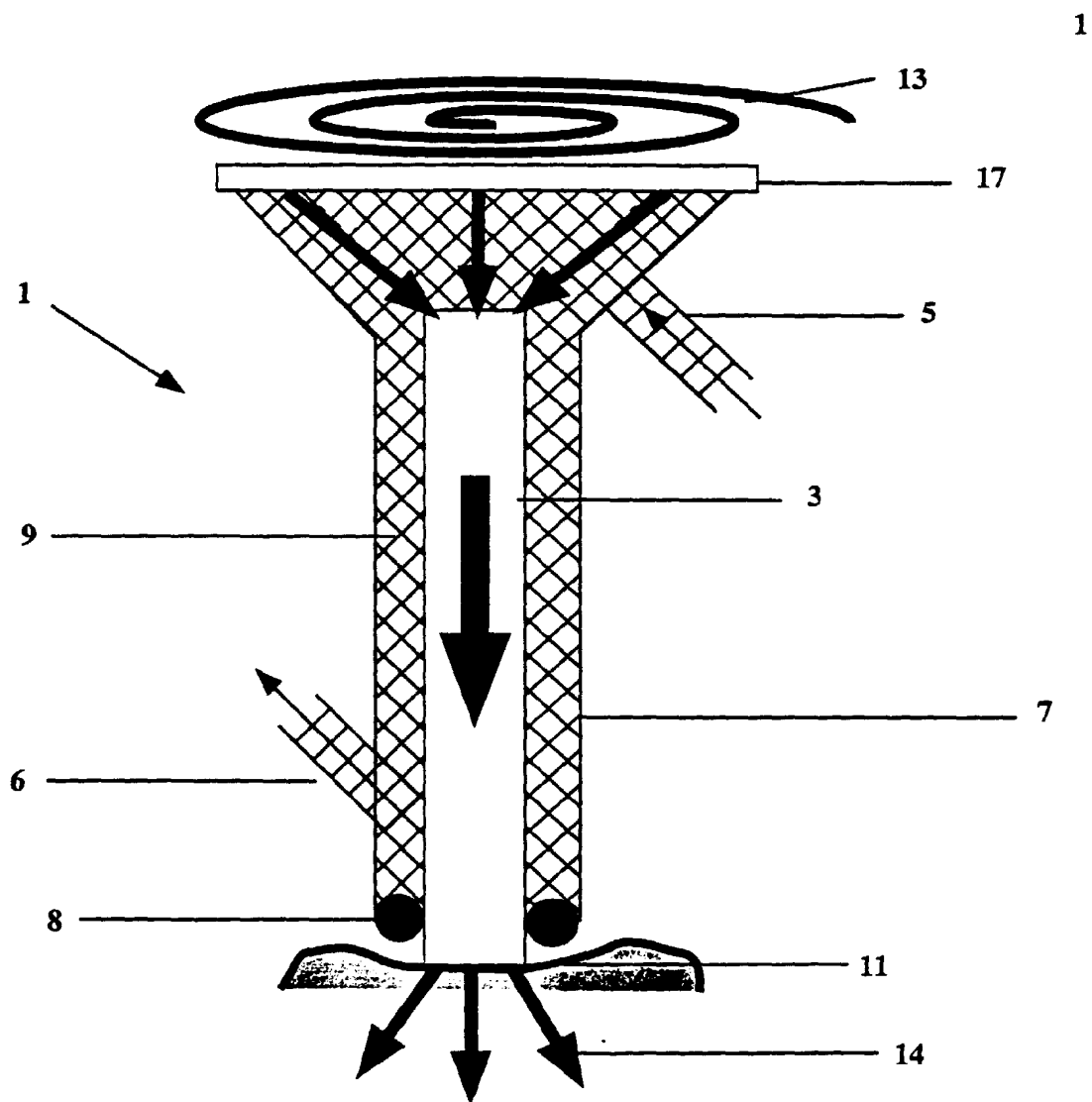
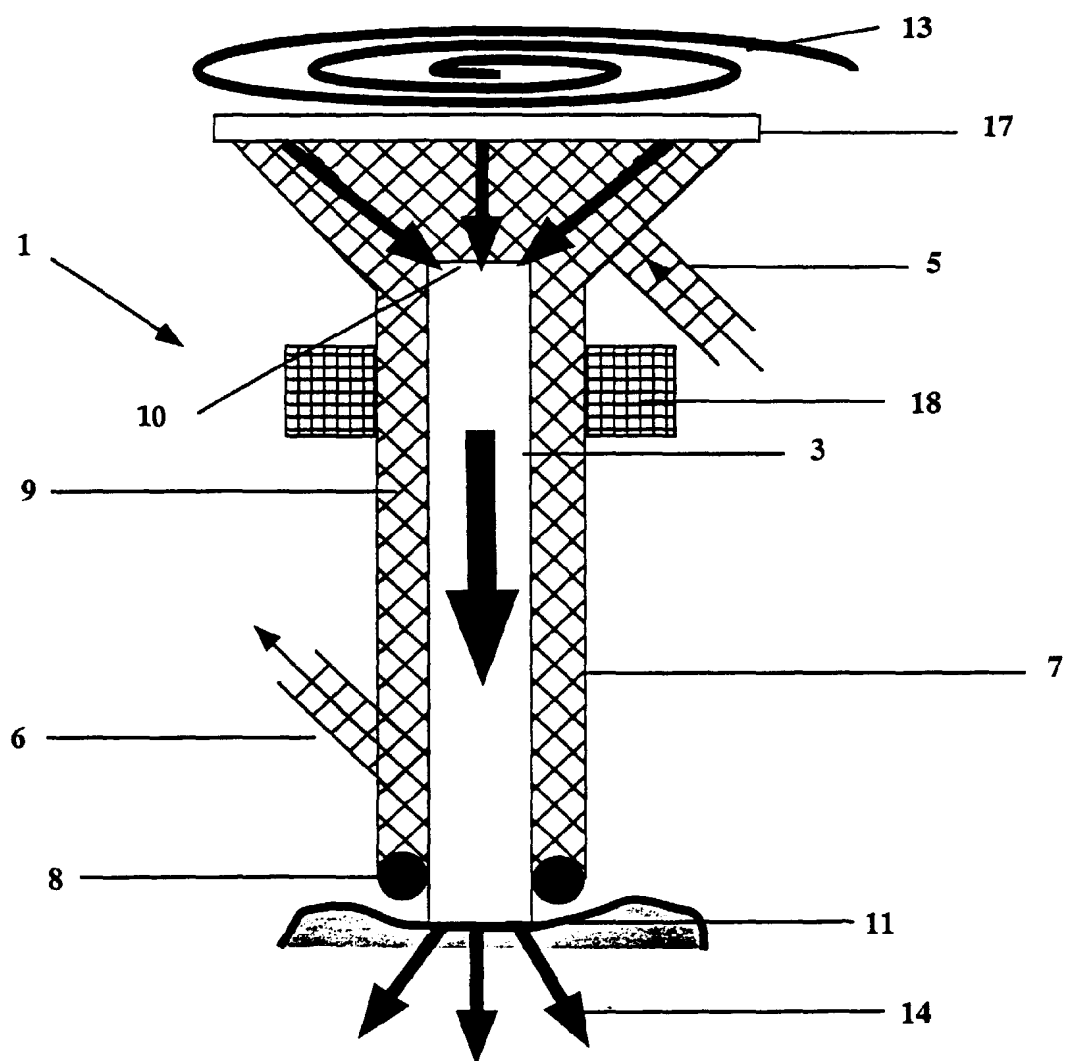


Fig.4



(19)



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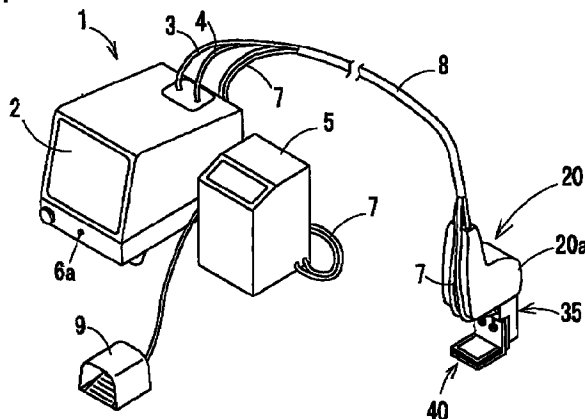
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### (54) **Laser skin treatment apparatus**

(57) A laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part is disclosed. The apparatus includes a laser irradiation unit (1, 20) provided with a laser irradiation optical system (4, 10, 21, 22, 23, 24, 25) for delivering the laser beam to the affected part, a contact member (40) including a contact face (42) which is brought into contact with at least one of the affected part and a periphery of the affected part, a cooling unit (35) for cooling at least the contact face (42) of the contact member (40), a detector (15, 31, 51,

51', 60, 70, 80) for detecting at least one of a temperature of a periphery of contact face (42) made contact with the affected part, a temperature of the contact member (40) or the cooling means (35), a contact state of the contact face (42) with respect to the affected part, and a relative substantially horizontal movement of the contact member (40) with respect to the affected part, and an irradiation controller (15) for controlling laser irradiation based on a result of detection by the detector.

**FIG.1**



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## Description

[0001] The present invention relates to a laser treatment apparatus which is used for treatment such as depilation, removal of wrinkles and birthmarks with a laser beam being irradiated to an affected part (a treatment part) of a patient.

[0002] When a laser treatment apparatus is used for performing treatment such as depilation to a patient by irradiating a laser beam to an affected part of the skin of the patient, the affected part is cooled before the laser irradiation in order to alleviate pain which would be caused by the laser irradiation. As such a method to cool the affected part, conventionally, there have been known a method of spraying nitrogen gas on the affected part and a method of decreasing the temperature of the affected part by making a cooling device contact with the affected part.

[0003] For execution of the laser irradiation, the positional relationship between the affected part and a laser irradiation unit such as a handpiece provided in the laser treatment apparatus must be stabilized. Therefore there has been known an apparatus arranged to have a support member (support base) which is brought into contact with the skin for stably supporting the irradiation unit. Furthermore, there is also an apparatus arranged to have a member serving both as the cooling device and the support member.

[0004] However, the above conventional apparatus may have possibilities that the laser irradiation is executed when an operator does not intend to do, for example, when the affected part is not sufficiently cooled or when the positional relationship between the affected part and the irradiation unit is not stabilized, etc. In such the cases, the unintentional laser irradiation may cause damage to the affected part and the parts outside thereof. The conventional apparatus is arranged to cool uniformly the affected part in spite of the condition thereof. Thus, the cooling could not be efficiently carried out.

[0005] The present invention has been made in view of the above circumstances and has an object to overcome the above problems and to provide a laser treatment apparatus capable of preventing laser irradiation under inappropriate conditions to an affected part of a patient, and capable of efficiently cooling the affected part.

[0006] Additional objects and advantages of the invention will be set forth in part in the description which follows and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

[0007] To achieve the purpose of the invention, there is provided a laser treatment apparatus which is used to treat an affected part of a patient by irradiating

a treatment laser beam to the affected part, the apparatus including: a laser irradiation unit provided with a laser irradiation optical system for delivering the laser beam to the affected part; a contact member including a contact face which is brought into contact with at least one of the affected part and a periphery thereof; cooling means for cooling at least the contact face of the contact member; detection means for detecting at least one of a temperature of a periphery of the contact face made contact with the affected part, a temperature of the contact member, a temperature of the cooling means, a contact state of the contact face with respect to the affected part, and a relative substantially horizontal movement of the contact member with, respect to the affected part; and irradiation control means for controlling laser irradiation based on a result of detection by the detection means.

[0008] In the above apparatus according to the present invention, the irradiation control means controls the laser irradiation based on the detection results by the detection means in order to irradiate the laser beam to the affected part only if appropriate conditions for the laser irradiation are satisfied. Accordingly, the laser beam can be prevented from irradiating the affected part under inappropriate conditions for the laser irradiation, thus preventing damage by the laser beam to the affected part of the patient and the parts outside the affected part.

[0009] Preferably, in the above laser treatment apparatus, the detection means includes first temperature detection means for detecting the temperature of the periphery of the contact face made contact with the affected part, and the apparatus further includes temperature control means for controlling cooling operations of the cooling means based on a result of detection by the first temperature detection means.

[0010] It is preferable that the detection means further includes contact detection means for detecting the contact state of the contact face with respect to the affected part and second temperature detection means for detecting the temperature of the contact member or the cooling means; and the temperature control means controls cooling operations of the cooling means based on a result of detection by the second temperature detection means when the contact detection means detects that the contact face of the contact member is apart from both of the affected part and the periphery thereof.

[0011] Preferably, the contact detection means detects the contact state of the contact face with respect to the affected part based on the result of detection by the first temperature detection means.

[0012] Preferably, the detection means includes a contact detection means for detecting the contact state of the contact face with respect to the affected part, and when the contact detection means detects that the contact face is in contact with at least one of the affected part and the periphery thereof, the irradiation control

means enables laser irradiation after a lapse of a predetermined time.

**[0013]** It is preferable that the detection means further includes temperature detection means for detecting the temperature of the periphery of the contact face made contact with the affected part, and the contact detection means detects the contact state of the contact face with respect to the affected part based on a result of detection by the temperature detection means.

**[0014]** Preferably, the detection means includes movement detection means for detecting a relative moving amount of the contact member in a substantially horizontal direction with respect to the affected part, and the irradiation control means precludes laser irradiation when the movement detection means detects that the moving amount of the contact member exceeds a predetermined reference.

**[0015]** According to another aspect of the present invention, there is provided a laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part, the apparatus including; a laser irradiation unit provided with a laser irradiation optical system for delivering the laser beam to the affected part; a contact member including a contact face which is brought into contact with at least one of the affected part and a periphery thereof; cooling means for cooling at least the contact face of the contact member; first temperature detection means for detecting a temperature of a periphery of the contact face made contact with the affected part; and temperature control means for controlling cooling operations of the cooling means based on a result of detection by the first temperature detection means.

**[0016]** It is preferably that the above laser treatment apparatus further includes contact detection means for detecting the contact state of the contact face of the contact member with respect to the affected part, second temperature detection means for detecting a temperature of the contact member or the cooling means; and when the contact detection means detects that the contact face is apart from both of the affected part and the periphery thereof, the temperature control means controls cooling operations of the cooling means based on a result of detection by the second temperature detection means.

**[0017]** Preferably, the contact detection means detects the contact state of the contact face of the contact member based on the result of detection by the first temperature detection means.

**[0018]** Preferably, the laser treatment apparatus further includes a support member for supporting the laser irradiation unit on the affected part, the support member including the contact member.

**[0019]** Preferably, the laser treatment apparatus further includes a laser transmission member made of material that is good in thermal conductivity and transmittable to the laser beam, wherein the contact face includes at least a face of the laser transmission mem-

ber.

**[0020]** The accompanying drawings, which are incorporated in and constitute a part of this specification illustrate an embodiment of the invention and, together with the description, serve to explain the objects, advantages and principles of the invention.

**[0021]** In the drawings,

Fig. 1 is a perspective view of a laser treatment apparatus in a first embodiment according to the present invention;

Fig. 2 is a sectional view of a cooling unit and a part of a scanner head of the apparatus in the embodiment;

Fig. 3 is a block diagram of main elements of a control system of the apparatus in the embodiment;

Fig. 4A is a bottom view of a window unit of the apparatus;

Fig. 4B is a bottom view of a window unit in another example;

Fig. 5 is a sectional view of showing a structure of indirectly detecting temperatures of an affected part in a second embodiment of the apparatus;

Fig. 6 is sectional view of showing a structure of detecting relative movements of a handpiece to the an affected part in a sixth embodiment of the apparatus;

Fig. 7A is a schematic view of an internal structure of a contact section, seen from bottom, in the sixth embodiment;

Fig. 7B is a front view of a rotating plate of the contact section in the sixth embodiment;

Fig. 8 is a schematic view of a structure of detecting temperatures of an affected part by use of a temperature sensor of a non-contact type in a third embodiment of the apparatus; and

Fig. 9 is a flowchart of showing laser irradiation control in a fourth embodiment of the apparatus.

**[0022]** A detailed description of a preferred embodiment of a laser treatment apparatus embodying the present invention will now be given referring to the accompanying drawings.

**[0023]** Fig. 1 is a perspective view of a laser treatment apparatus in a first embodiment according to the present invention.

**[0024]** A main unit 1 of the laser treatment apparatus is provided with a large-size liquid crystal display (LCD) 2 at the front face. The LCD 2 is a touch panel whereby an operator can input various settings by depressing operation keys (items) displayed on a screen. A communication cable 3 and a fiber cable 4 are provided extending from the top of the main unit 1 to a handpiece 20 to connect therebetween.

**[0025]** Inside of the main unit 1, there are provided a laser source 10, a laser source 11, and others (see Fig. 3). The laser source 10 emits a near-infrared laser beam of a wavelength of 800-820nm. This laser beam is

used for depilation as a treatment laser beam. The laser source 11 emits a red visible laser beam of a wavelength of 620-650nm, which is used for aiming. The laser beams emitted from the laser sources 10 and 11 are delivered to the handpiece 20 through the fiber cable 4.

**[0026]** The handpiece 20 is constructed of a scanner head 20a containing an optical system and others for allowing the laser beam delivered thereto through the fiber cable 4 to scan, and a cooling unit 35 for cooling the skin of a patient by contacting with the skin.

**[0027]** Numeral 5 is a chiller for supplying coolant to the handpiece 20 (the cooling unit 35). Two tubes 7 connected with the chiller 5 are made into a bundle together with the communication cable 3 and the fiber cable 4, forming a single convergence cable 8 connected to the handpiece 20. Numeral 9 is a footswitch for generating a trigger signal to instruct start of laser irradiation. Numeral 6a is an indication lamp for informing the operator of that the laser beam is enabled to be irradiated. Numeral 6b is an indication buzzer for informing the operator of the same (see Fig. 3).

**[0028]** Fig. 2 is a sectional view of the cooling unit 35 and a part of the scanner head 20a of the handpiece 20. This scanner head 20a includes a first mirror 23 and a second mirror 24. Those first and second mirrors 23 and 24 are rotated (swung) by a first galvanometer 23a and a second galvanometer 24a respectively to deflect a laser beam to move an irradiating point in an X- and Y- directions. The laser beam is thus allowed to scan a wide area.

**[0029]** The laser beam delivered from the main unit 1 through the fiber cable 4 enters the scanner head 20a, wherein the beam is deflected by a mirror 21 and made into parallel luminous flux by a collimator lens 22. Then, the luminous flux is deflected by the first and second mirrors 23 and 24 to move the irradiating point in the X- and Y- directions, passing through a condenser lens 25, thereby forming a circular spot beam, which is of a diameter of about 5mm in the present embodiment. The laser beam is irradiated as the spot beam onto the affected part (treatment part).

**[0030]** It is to be noted that the position and the focal distance of the condenser lens 25 are determined such that the laser beam projected from the scanner head 20a is focused on or near an underside of a first window 42 (i.e., a contact side with the affected part). Therefore, when the cooling unit 35 (the first window 42) is made contact with the affected part, the scanner head 20a can stably be held at a substantially constant distance from the affected part. The cooling unit 35 also serves as a support member for supporting the scanner head 20a.

**[0031]** The cooling unit 35 is constructed of a scanner support base 26 and a window unit 40. The support base 26 is made of polyacetal resin which has an excellent heat-insulating property. This support base 26 is fixed under the scanner head 20a. A window fixing plate

27 made of aluminum which is good in thermal conductivity is disposed inside the base 26 and is fastened to the base 26 by screws tightened from the side of the base 26 (i.e., perpendicularly to the drawing paper of Fig. 2). Numeral 28 is a Peltier element which is an electronic heat exchanger. This Peltier element 28 is disposed between the fixing plate 27 and a cooling plate 29 made of aluminum and disposed in the base 26. A current is applied to the Peltier element 28 to pass there-through so that the side contacting with the fixing plate 27 functions as a heat-absorbing side (a cooling side), while the opposite side contacting with the cooling plate 29 functions as a heat-radiating side. The cooling plate 29 is provided therein with a flow passage through which the coolant circulates. The coolant cooled in the chiller 5 is delivered to the cooling unit 35 through the tubes 7 and fed to the cooling plate 29 through a water pipe 30 provided in the cooling unit 35, circulating through the inside of the cooling plate 29. The cooling plate 29 can thus absorb the heat radiated from the Peltier element 28.

**[0032]** Numeral 31 is a second temperature sensor attached to the lower end of the fixing plate 27. This second temp. sensor 31 detects the temperature of the fixing plate 27. The controller 15 controls the temperature of the Peltier element 28 based on the result of detection by the second temp. sensor 31. The detail thereof will be described later.

**[0033]** The window unit 40 is constructed of a window frame 41, the first window 42, a heat-insulating board 43, a second window 44, a cover 45. The details of those members are as follows.

**[0034]** The first window 42 is made of transparent sapphire glass which is good in thermal conductivity. This first window 42 is brought into contact with the skin of the patient for the laser treatment. The window frame 41 has a substantially L-shaped section as shown in Fig. 2, including a vertical part 41a and a horizontal part 41b, and holds the first window 42 in the horizontal part 41b. The heat-insulating board 43 is made of polyacetal resin which has a good heat-insulating property. This board 43 is given the shape of a rectangular frame. The second window 44 is made of transparent glass which is inferior to the first window 42 in thermal conductivity, for example, BK7 (the classification symbol of SHOT Co.) generally used as optical glass. The cover 45 is made of aluminum and has an opening. The window unit 40 having the above arrangement can transmit the laser beam discharged from the scanner head 20a toward the affected part.

**[0035]** The window frame 41 is made of aluminum which is good in thermal conductivity. The vertical part 41a of the frame 41 is formed with two U-shaped slots (not shown) in the upper portion. Thus, the frame 41 is detachably secured to the fixing plate 27 by two screws 32 passing through the two slots and are threaded into the fixing plate 27. Such the arrangement enables attachment of a suitable window unit according to pur-

poses. Detaching the window frame 41 can be easily done by only loosening the screws 32 a little, without fully removing the screws 32, thereby allowing the frame 41 to move downward. On the other hand, attaching the window frame 41 is made by sliding the vertical part 41a of the frame 41 along the fixing plate 27 until the two U-shaped slots of the vertical part 41a are engaged with the two screws 32, and then tightening the screws 32. As cooled by the Peltier element 28, the fixing plate 27 cools the window frame 41 contacting therewith, thus cooling the first window 42.

**[0036]** The window frame 41 is formed with an opening in the horizontal part 41b formed horizontally extending and shaped as a rectangular frame. In the underside of the horizontal part 41b, the first window 42 is fitted with adhesive of good thermal conductivity. This first window 42 in the present embodiment is a square of about 40mm per side. On the upside of the horizontal part 41b, the heat-insulating board 43 is disposed and, furthermore, the second window 44 is fixed on the board 43 with adhesive of a good heat-insulating property to be shielded from the cooling. The cover 45 is adhered to the second window 44 to cover all the above members. With such the arrangement, there is provided a sealed space 48 (indicated by a dotted line in Fig. 2) which serves as a heat-insulating layer between the first and second windows 42 and 44 to enhance the heat-insulation effect between the windows configured as a double-window construction. Accordingly, even if the first window 42 is allowed to cool, the second window 44 will not easily cool. This can prevent the generation of condensation on the upper surface of the second window 44.

**[0037]** Numeral 50 is a heat-insulating board 50 made of polyacetal resin which has a good heat-insulating property. This board 50 is disposed, as shown in Fig. 2, between the window frame 41 and a first temperature sensor 51 and between the first window 42 and the first temp. sensor 51 to prevent the first temp. sensor 51 from making contact with both of the window frame 41 and the first window 42.

**[0038]** The first temp. sensor 51 is constructed of a sheet-type thermistor. This sensor 51 is attached to the window frame 41 along the frame shape of the bottom surface of the horizontal frame part 41b (see Fig. 4A) so that the surface of the first temp. sensor 51, opposite to the surface contacting with the heat insulating plate 50, becomes substantially flush with the bottom surface of the first window 42. Thus, when the bottom surface of the first window 42 is brought into contact with the skin of the patient, the surface of the first temp. sensor 51 makes contact with the skin at the same time, enabling detection of the temperature of the skin (the periphery of the affected part).

**[0039]** It is to be noted that although the first temp. sensor 51 is a sheet-type thermistor in the present embodiment, it is not limited thereto and may be modified to different arrangements if only the surface thereof can make contact with the skin to detect the tempera-

ture thereof at the same time when the bottom surface of the first window 42 is brought into contact with the skin. One example of such the arrangements is shown in Fig. 4B. In Fig. 4B, a first temp. sensor 51' is constructed to detect the temperature of a point on the skin.

**[0040]** The first temp. sensor 51 is connected to the communication cable 3 through a connection cable not shown and a connector. At the time of detaching the window unit 40, the connection cable is disconnected from the connector. This also enables an exchange of window units without any trouble.

**[0041]** Similarly to the case of the second temp. sensor 31 mentioned above, the controller 15 controls the temperature of the Peltier element 28 based on the detection result by the first temp. sensor 51. The detail thereof will be described later.

**[0042]** Numeral 46 is a heat-insulating board made of polyacetal resin and is fixedly attached to the vertical part 41a of the window frame 41 for preventing the window frame 41 from absorbing extraneous heat and also for heat-insulating the second window 44.

**[0043]** Next, operation of the laser treatment apparatus constructed as above will be described with reference to Fig. 3 which is a block diagram of main elements of a control system of the apparatus in the present embodiment.

**[0044]** The first galvanometer 23a, the second galvanometer 24a, the second temp. sensor 31, the first temp. sensor 51, the Peltier element 28, and others are connected to the controller 15 through the communication cable 3.

**[0045]** An operator operates setting keys displayed on the LCD panel 2 to set irradiation conditions for preparation for laser irradiation. While the first window 42 is not in contact with, or is apart from the affected part of the patient, the controller 15 controls the temperature of the Peltier element 28 so that a predetermined value is constantly detected by the second temp. sensor 31.

**[0046]** The contact/noncontact of the first window 42 with the affected part can be judged based on the result of temperature detection by the first temp. sensor 51. For instance, the threshold value for detection of the contact of the first window 42 with the affected part is set at 30°C. When the first temp. sensor 51 detects the temperature more than 30°C, the controller 15 judges that the first window 42 is in contact with the affected part. Alternatively, a contact sensor (a touch sensor) may be provided in the part or surface of the window unit 40 which is made contact with the skin.

**[0047]** While the controller 15 controls the temperature of the Peltier element 28 based on the result of temperature detection by the second temp. sensor 31, the controller 15 controls (interlocks) the laser source 10 to prevent the laser irradiation even if a trigger signal of instructing the laser irradiation is input from the footswitch 9. Alternatively, instead of direct driving of the laser source 10, a safety shutter may be controlled to be inserted into or removed from an optical path of the

laser beam.

**[0048]** The operator, after preparation of the main unit 1 for laser irradiation, holds the handpiece 20 by hand to bring the first window 42 into contact with the affected part (skin). Then, the controller 15 receives the result of detection by the first temp. sensor 51 and determines whether the detected temperature is equal to or more than the threshold value to detect the contact of the first window 42 with the affected part. When the detected temperature is the threshold value or more, the controller 15 recognizes that the first window 42 is in contact with the affected part. Upon recognition of the contact of the first window 42 with the affected part, the controller 15 stops control of the temperature of the Peltier element 28 based on the detection result by the second temp. sensor 31 and, alternatively, starts the control of the temperature of the Peltier element 28 based on the detection result by the first temp. sensor 51.

**[0049]** Contacting with the first window 42, the affected part is gradually cooled due to heat-absorption by the first window 42. The temperature variation occurring in the affected part also causes the temperature of the periphery of the affected part to decrease. The first temp. sensor 51 detects the temperature variation in the affected part and the periphery thereof.

**[0050]** When the temperature of the affected part detected by the first temp. sensor 51 does not reach an appropriate value (for example, 5°C in the present embodiment, which is referred to as a predetermined temperature) for laser irradiation, the controller 15 controls the temperature of the Peltier element 28 (the heat-absorbing side, or the cooling side) to further decrease regardless of the temperature detected by the second temp. sensor 31.

**[0051]** Decreasing the temperature of the heat-absorbing side of the Peltier element 28 enhances the heat-absorbing effect of the first window 42. This makes it possible to shorten the time needed until the temperature of the affected part reaches (decreases to) the predetermined temperature. When the detected temperature by the first temp. sensor 51 reaches the predetermined temperature, the controller 15 stops cooling the Peltier element 28. Simultaneously, the controller 15 releases the interlock of the laser source 10 to enable the laser beam to be irradiated to the affected part. Alternatively, the safety shutter may be removed from the optical path for enabling laser irradiation. The controller 15 causes the indication lamp 6a to light up and the indication buzzer 6b to sound in order to inform the operator of that the temperature of the affected part has reached the predetermined temperature and the laser irradiation is enabled.

**[0052]** After the indication by the lamp 6a and the buzzer 6b, the operator may instruct the laser irradiation by depressing the footswitch 9. Upon receipt of the trigger signal from the footswitch 9, the controller 15 controls the first and second galvanometers 23a and 24a respectively to allow the laser beam emitted from the

laser source 10 to scan a selected scanning area in the treatment part while irradiating. Alternatively, the controller 15 may be arranged to automatically start the laser irradiation upon release of the interlock of the laser source 10.

**[0053]** Upon completion of the laser irradiation, the first window 42 (the handpiece 20) is moved away from the affected part. This causes sudden variation in temperature detected by the first temp. sensor 51 because the sensor 51 detects the room temperature. When the controller 15 obtains a predetermined or more temperature variation (for example, a 5°C or more variation) in the detection result by the sensor 51 after completion of the laser irradiation, the controller 15 recognizes that the first window 42 has been moved away from the affected part, and controls the temperature of the Peltier element 28 based on the detected temperature by the second temp. sensor 31.

**[0054]** In the above first embodiment, the temp. sensor (the first temp. sensor 51) is provided near the first window 42 to directly detect a variation in temperature of the affected part. With this detection manner, the laser irradiation is controlled so that it is precluded until the detected temperature reaches the predetermined value. However the laser irradiation may also be controlled by the arrangements other than that described above. Some examples thereof will be described below.

**[0055]** In a second embodiment, the laser irradiation is controlled by indirect detection of the temperature of the affected part, instead of the direct detection of the same in the first embodiment. This indirect detection is executed by detecting a variation in temperature of the first window 42.

**[0056]** In the present embodiment, a temperature sensor 60 for detecting the internal temperature of the first window 42 is provided in the first window 42 at a position where the sensor 60 does not prevent the scanning of the laser beam (see Fig. 5). When the first window 42 held at a predetermined temperature is made contact with the skin, the temperature of the window 42 rises once. The window 42 is then cooled by the Peltier element 28 into the predetermined temperature again. The controller 15 enables the laser irradiation when the temperature of the window 42 returns to the predetermined value (or reaches a permissible range of the predetermined temperature). In this case, the temp. sensor 60 is preferably disposed inside the first window 42 closer to the bottom surface (as closer as possible to the affected part), thus enabling speedup in detection of temperature variation.

**[0057]** In a third embodiment, a noncontact type temperature sensor is used to detect the temperature of the affected part through the first window 42 and others. This arrangement is shown in Fig. 8, where like elements corresponding to those in Fig. 2 are indicated by like numerals. Numeral 80 is a temperature sensor disposed in the scanner head 20a. The sensor 80 detects infrared energy radiated from the affected part to detect



the temperature of the affected part. Numeral 81 is a half mirror which reflects the major part of the laser beam, while transmitting an infrared light from the affected part.

**[0058]** In the above embodiments, the laser irradiation is controlled based on the temperature of the affected part, but it is not limited thereto. It may be arranged, for example, such that the laser irradiation is enabled when a predetermined time elapses after detection that the first window 42 is in contact with the affected part. The control in this case is explained below as a fourth embodiment referring to Fig. 9 showing a flowchart of the laser irradiation control.

**[0059]** After preparation of the main unit 1 (S1), the operator holds the handpiece 20 to bring the first window 42 into contact with the affected part. The controller 15 then determines whether the detected temperature by the first temp. sensor 51 (or the temp. sensor 60 or 80) is the threshold value or more (S2). When the detected temperature is the threshold value or more, the controller 15 recognizes that the first window 42 is in contact with the affected part (S2: YES). The controller 15 enables the laser irradiation after a lapse of a predetermined time (for example, 2 seconds in the present embodiment).

**[0060]** This predetermined time can be determined in the following manner. The first window 42 is in advance made contact with some different positions in the affected part to obtain a time needed until the temperature at each position reaches a proper value. Thus the controller 15 quantitatively determines the predetermined time. It may be arranged such that the controller 15 simultaneously detects a temperature variation occurring in the affected part through the first temp. sensor 51 (or the temp. sensor 60 or 80) and, when the temperature reaches the predetermined value before a lapse of the predetermined time, the laser irradiation is enabled even if the predetermined time does not lapse yet.

**[0061]** Furthermore, in a fifth embodiment, the laser irradiation may be controlled by only detection of contact/noncontact of the first window 42 with the affected part. In this case, the controller 15 detects the contact state of the window 42 based on a temperature variation detected by the first temp. sensor 51 (or the temp. sensor 60 or 80). The laser irradiation can thus be controlled based on the detection result by the sensor 51. Alternatively, two electrodes may be provided in a face of the window unit 40 which makes contact with the affected part, allowing the controller 15 to detect variation in current or resistance which occurs when the electrodes come into contact with the affected part. Instead thereof, a pressure detecting element may be used to allow the controller 15 to determine the contact/noncontact state of the first window 42, for example, by detecting a pressure exerted on the first window 42 when made contact with the affected part.

**[0062]** In a sixth embodiment, on the other hand,

the laser irradiation control can be executed if the handpiece 20 and the patient unintentionally move even during the laser irradiation. This arrangement is explained below with reference to Fig. 6. Fig. 6 shows the structure of the handpiece 20 shown in Fig. 2 with a contact section 70 added. Like elements corresponding to those in Fig. 2 are indicated by like numerals. The contact section 70 is provided with detecting members for detecting the contact state of the first window 42 with the affected part and the movement thereof in a substantially horizontal direction.

**[0063]** To be more specific, at the underside of the contact section 70 are provided a ball 71 and a microswitch 72. The ball 71 is rotatably held in the contact section 70 so as to partially protrude out of a housing of the contact section 70. The microswitch 72 is turned on when the underside of the contact section 70 comes into contact with the affected part.

**[0064]** Fig. 7A is a schematic view of the internal structure of the contact section 70, seen from bottom. Rollers 73a and 73b are rotatably provided in contact with the ball 71, both rollers being disposed in directions intersecting at right angles. Rolling of the ball 71 causes the rollers 73a and 73b to rotate respectively. Numerals 74a and 74b are rotating discs which are attached to shafts 75a and 75b of the rollers 73a and 73b, respectively. By rotation of the rollers 73a and 73b, the rotating discs 74a and 74b are rotated in the same directions as those of the rollers 73a and 73b.

**[0065]** Each of the rotating discs 74a and 74b is provided with a plurality of slits 77 circumferentially spaced as shown in Fig. 7B. Numerals 76a and 76b are photosensors, each of which is constructed of a light projecting element and a light receiving element. The photosensor 76a (76b) is disposed so that the rotating disc 74a (74b) is partially inserted between the light projecting element and the light receiving element. This mechanism is substantially similar to a movement detecting mechanism of a mouse generally used in personal computers.

**[0066]** The microswitch 72 and the photosensors 76a and 76b are connected to the controller 15 through the communication cable 3.

**[0067]** After preparation of the main unit 1 for the laser irradiation in a similar manner to the above embodiments, the operator moves the handpiece 20 by hand to bring the first window 42 into contact with the affected part. When the first window 42 is made contact with the affected part, pressing the microswitch 72, thereby transmitting a relevant signal to the controller 15 through the communication cable 3.

**[0068]** If the controller 15 has not received the signal from the microswitch 72, alternatively, if the temperature of the affected part has not reached the predetermined value, the controller 15 controls (interlocks) the laser source 10 to preclude the irradiation of the laser beam even if the trigger signal of instructing the laser irradiation is input.

**[0069]** Even though the laser irradiation is enabled and executed, the handpiece 20 or the patient unintentionally moves or shifts in some cases, thereby causing the contact section 70 to separate from the affected part. The microswitch 72 is thus turned off. Receiving no signal from the microswitch 72, the controller 15 stops the laser irradiation.

**[0070]** If the contact section 70 is moved in a substantially horizontal direction though it is maintained contact with the affected part, the interlock is also established due to the rolling of the ball 71 of the contact section 70 in correspondence to the moving amount of the contact section 70.

**[0071]** The rolling of the ball 71 causes the rollers 73a and 73b to rotate. The rotation of the roller 73a (73b) is transmitted to the rotating disc 74a (74b). The rotation of the disc 74a (74b) is detected by the photosensor 76a (76b), which transmits a detection signal to the controller 15. The controller 15 detects that the contact section 70 (namely, the handpiece 20) is relative moved with respect to the affected part based on the input detection signal in comparison with the signal from the photosensors 76a and 76b at the time of input of the trigger signal from the footswitch 9. The controller 15 stops the laser irradiation when the moving amount of the contact section 70 exceeds a predetermined amount. This moving amount can be obtained in the following manner. By the rotation of the rotating disc 74a (74b), the luminous flux projected by the light projecting element of the photosensor 76a (76b) is pulsed and received by the receiving element. The moving amount is thus calculated based on the number of pulses detected by the photosensor 76a (76b).

**[0072]** The above control can establish the interlock to stop the laser irradiation if the patient or the handpiece 20 unintentionally moves even during the laser irradiation, enabling the prevention of the laser irradiation to any parts other than the intended part.

**[0073]** As described above, in the above embodiments according to the present invention, the temperatures of the affected part and others are detected by the temp. sensors to prevent the laser irradiation to the affected part if it is not cooled enough for the laser irradiation, thereby reducing damage to the skin of the patient.

**[0074]** Detecting the contact/noncontact of the first window 42 with the affected part and the relative horizontal movement of the handpiece with respect to the affected part, the controller 15 operates to stop the laser irradiation when the affected part moves even during the laser irradiation. This makes it possible to prevent damage by the laser beam to unintended parts outside the affected part to be irradiated.

**[0075]** The present invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof.

**[0076]** The foregoing description of the preferred embodiment of the invention has been presented for

purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and modifications and variations are possible in light of the above teachings or may be acquired from practice of the invention. The embodiment chosen and described in order to explain the principles of the invention and its practical application to enable one skilled in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims appended hereto, and their equivalents.

## Claims

1. A laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part, the apparatus including:

a laser irradiation unit (1, 20) provided with a laser irradiation optical system (4, 10, 21, 22, 23, 24, 25) for delivering the laser beam to the affected part;

a contact member (40; 41, 42, 43, 44, 45, 46, 48, 50) including a contact face (42) which is brought into contact with at least one of the affected part and a periphery thereof;

cooling means (35; 5, 7, 27, 28, 29, 30) for cooling at least the contact face (42) of the contact member (40);

detection means (15, 31, 51, 51', 60, 70, 80) for detecting at least one of a temperature of a periphery of the contact face (42) made contact with the affected part, a temperature of the contact member (40), a temperature of the cooling means (35), a contact state of the contact face (42) with respect to the affected part, and a relative substantially horizontal movement of the contact member (40) with respect to the affected part; and

irradiation control means (15) for controlling laser irradiation based on a result of detection by the detection means.

2. The laser treatment apparatus according to claim 1, wherein the detection means includes first temperature detection means (51, 51', 60, 80) for detecting the temperature of the periphery of the contact face (42) made contact with the affected part, and the apparatus further includes temperature control means (15) for controlling cooling operations of the cooling means (35) based on a result of detection by the first temperature detection means (51, 51', 60, 80).

3. The laser treatment apparatus according to claim 2, wherein the detection means further includes:

contact detection means (15) for detecting the contact state of the contact face (42) with respect to the affected part; and

second temperature detection means (31) for detecting the temperature of the contact member (40) or the cooling means (35); and the temperature control means (15) controls cooling operations of the cooling means (35) based on a result of detection by the second temperature detection means (31) when the contact detection means (15) detects that the contact face (42) of the contact member (40) is apart from both of the affected part and the periphery thereof.

4. The laser treatment apparatus according to claim 3, wherein the contact detection means (15) detects the contact state of the contact face (42) with respect to the affected part based on the result of detection by the first temperature detection means (51, 51', 60, 80).
5. The laser treatment apparatus according to claim 1, wherein the detection means includes contact detection means (15) for detecting the contact state of the contact face (42) with respect to the affected part, and when the contact detection means (15) detects that the contact face (42) is in contact with at least one of the affected part and the periphery thereof, the irradiation control means (15) enables laser irradiation after a lapse of a predetermined time.
6. The laser treatment apparatus according to claim 5, wherein the detection means further includes temperature detection means (51, 51', 60, 80) for detecting the temperature of the periphery of the contact face (42) made contact with the affected part, and the contact detection means (15) detects the contact state of the contact face (42) with respect to the affected part based on a result of detection by the temperature detection means (51, 51', 60, 80).
7. The laser treatment apparatus according to claim 1, wherein the detection means includes movement detection means (70; 71, 73, 74, 75, 76) for detecting a relative moving amount of the contact member (40) in a substantially horizontal direction with respect to the affected part, and the irradiation control means (15) precludes laser irradiation when the movement detection means (70) detects that the moving amount of the contact member (40) exceeds a predetermined reference.
8. A laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part, the apparatus

including:

a laser irradiation unit (1, 20) provided with a laser irradiation optical system (4, 10, 21, 22, 23, 24, 25) for delivering the laser beam to the affected part;  
a contact member (40) including a contact face (42) which is brought into contact with at least one of the affected part and a periphery thereof;  
cooling means (35) for cooling at least the contact face (42) of the contact member (40);  
first temperature detection means (51, 51', 60, 80) for detecting a temperature of a periphery of the contact face (42) made contact with the affected part; and  
temperature control means (15) for controlling cooling operations of the cooling means (35) based on a result of detection by the first temperature detection means (51, 51', 60, 80).

9. The laser treatment apparatus according to claim 8 further including:

contact detection means (15) for detecting the contact state of the contact face (42) of the contact member (40) with respect to the affected part;  
second temperature detection means (31) for detecting a temperature of the contact member (40) or the cooling means (35); and  
wherein when the contact detection means (15) detects that the contact face (42) is apart from both of the affected part and the periphery thereof, the temperature control means (15) controls cooling operations of the cooling means (35) based on a result of detection by the second temperature detection means (31).

10. The laser treatment apparatus according to claim 9, wherein the contact detection means (15) detects the contact state of the contact face (42) of the contact member (40) based on the result of detection by the first temperature detection means (51, 51', 60, 80).
11. The laser treatment apparatus according to any one of claims 1 to 10 further including a support member (35) for supporting the laser irradiation unit (20) on the affected part, the support member (35) including the contact member (40).
12. The laser treatment apparatus according to any one of claims 1 to 11 further including a laser transmission member (42, 44) made of material that is good in thermal conductivity and transmittable to the laser beam, wherein the contact face (42) includes at least a

face of the laser transmission member.

5

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35

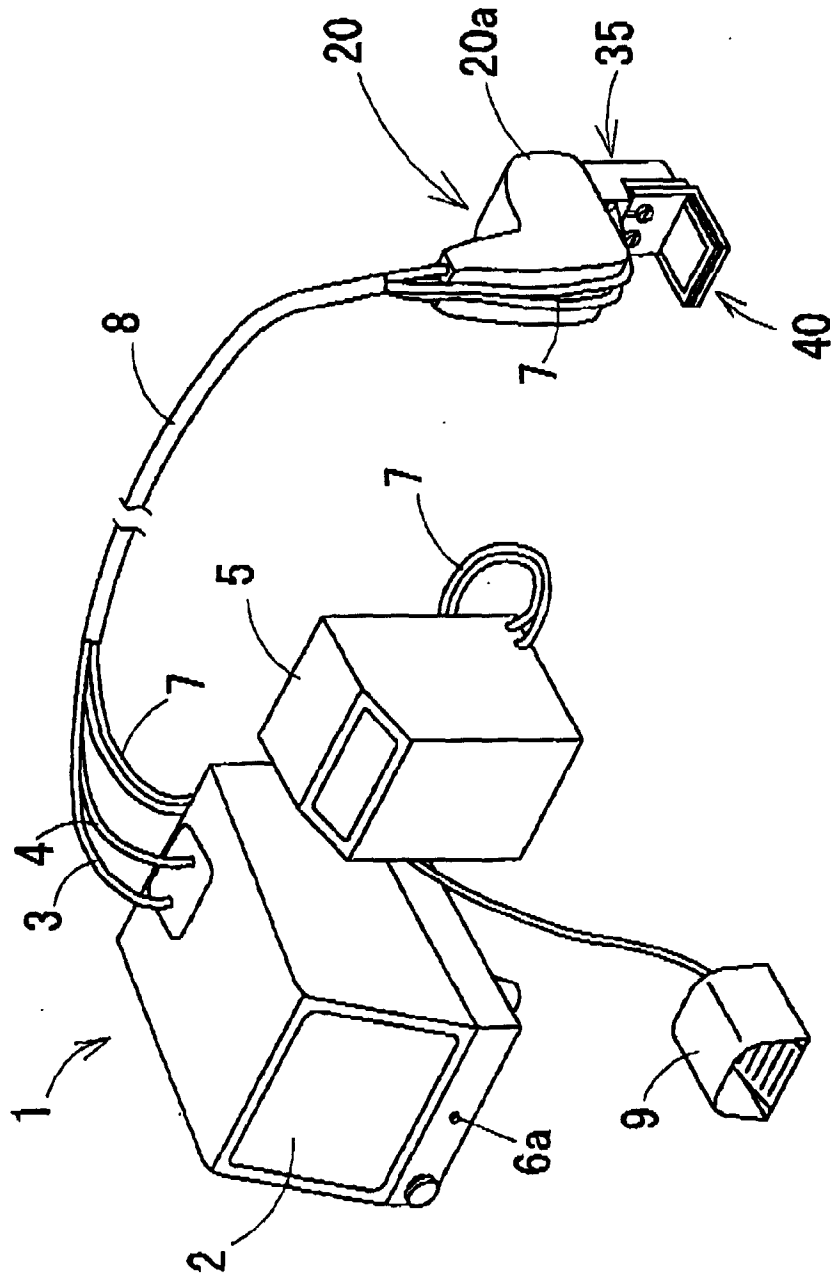
40

45

50

55

FIG.1



**FIG.2**

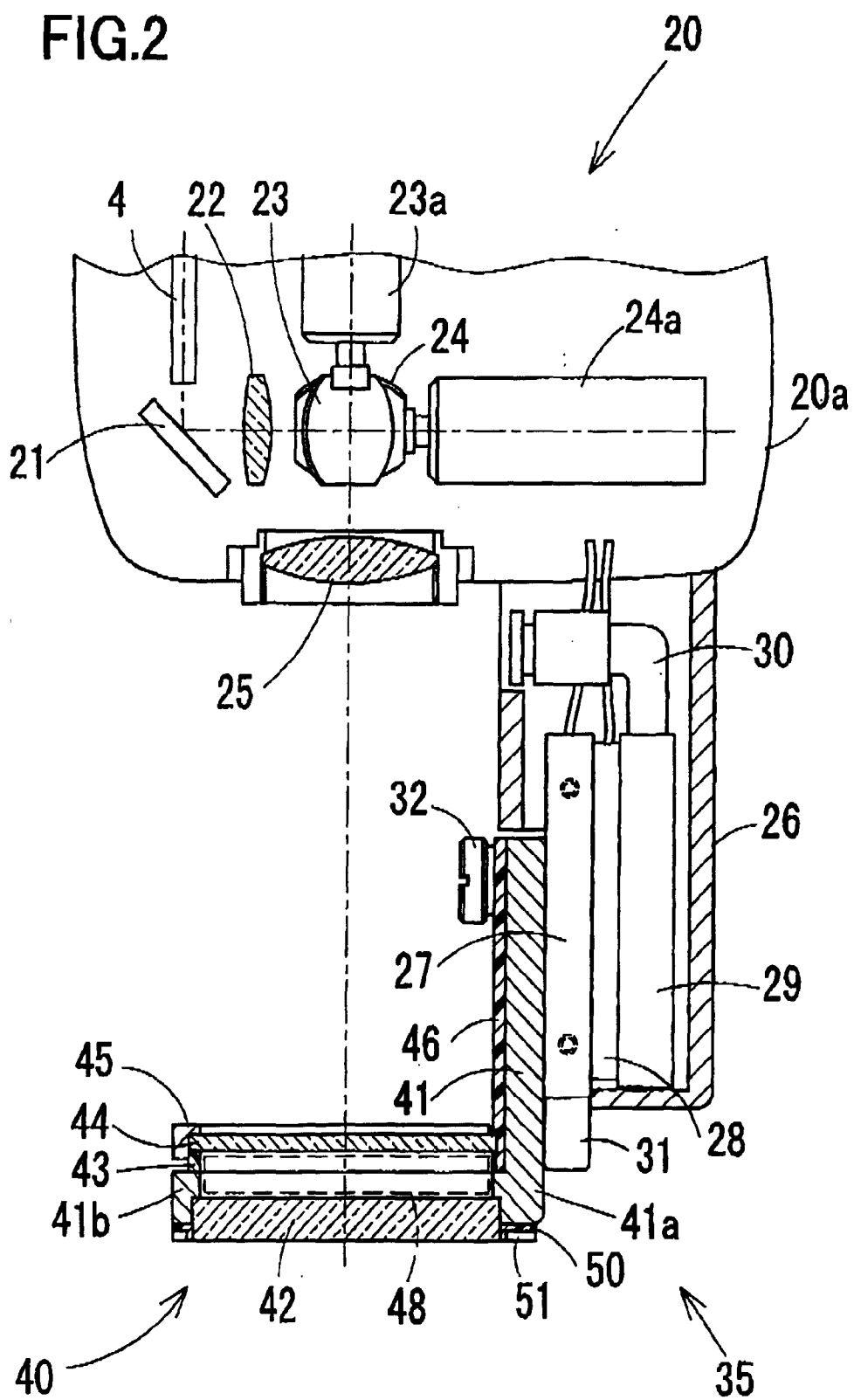


FIG.3

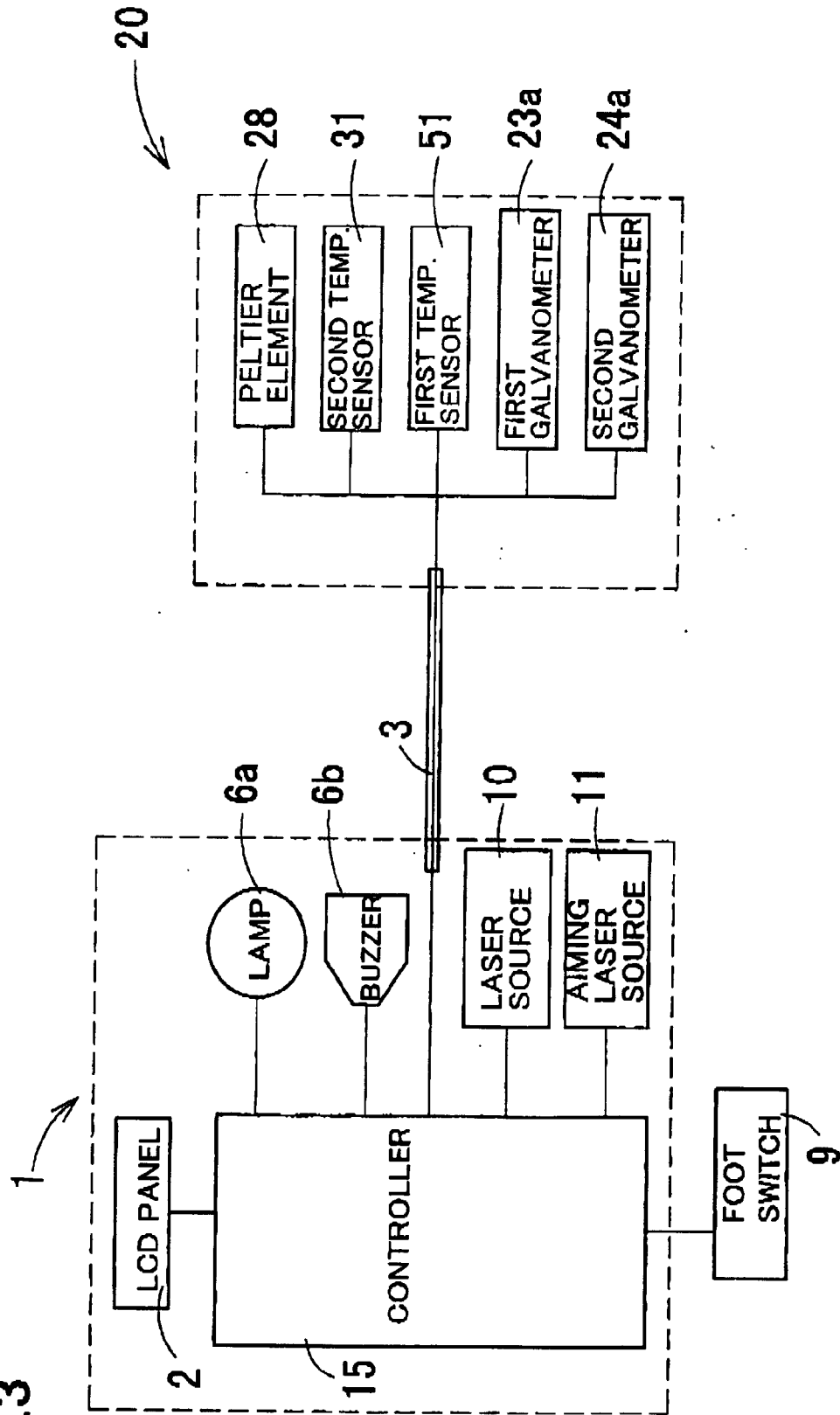


FIG.4A

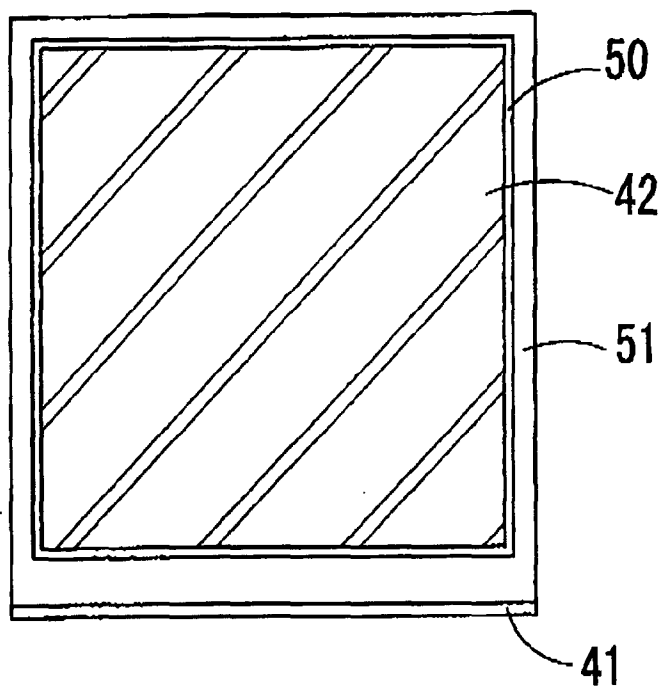


FIG.4B

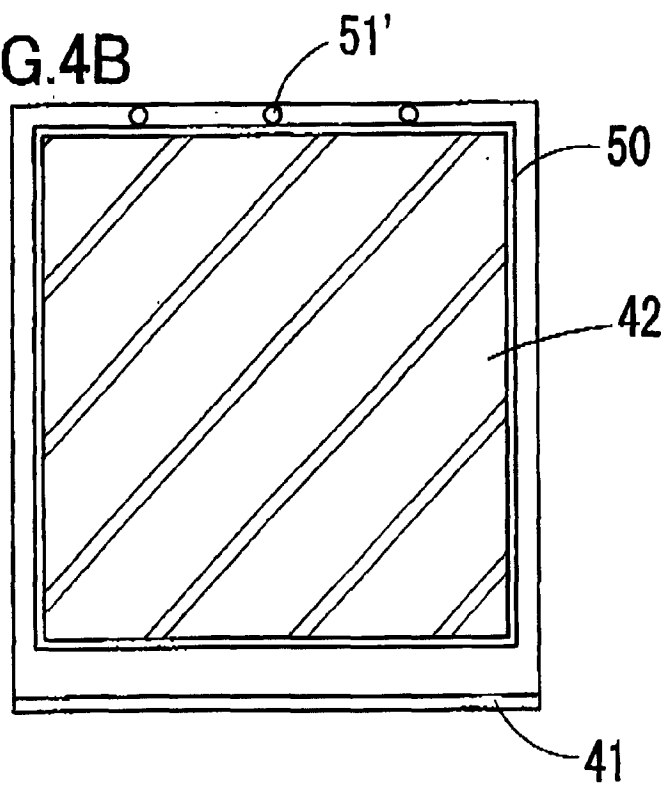




FIG.5

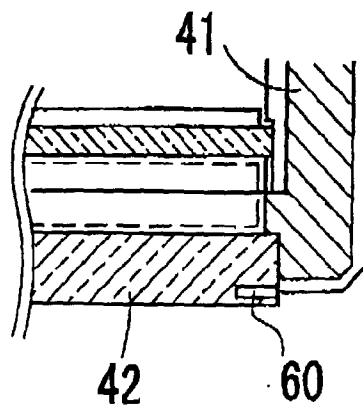


FIG.6

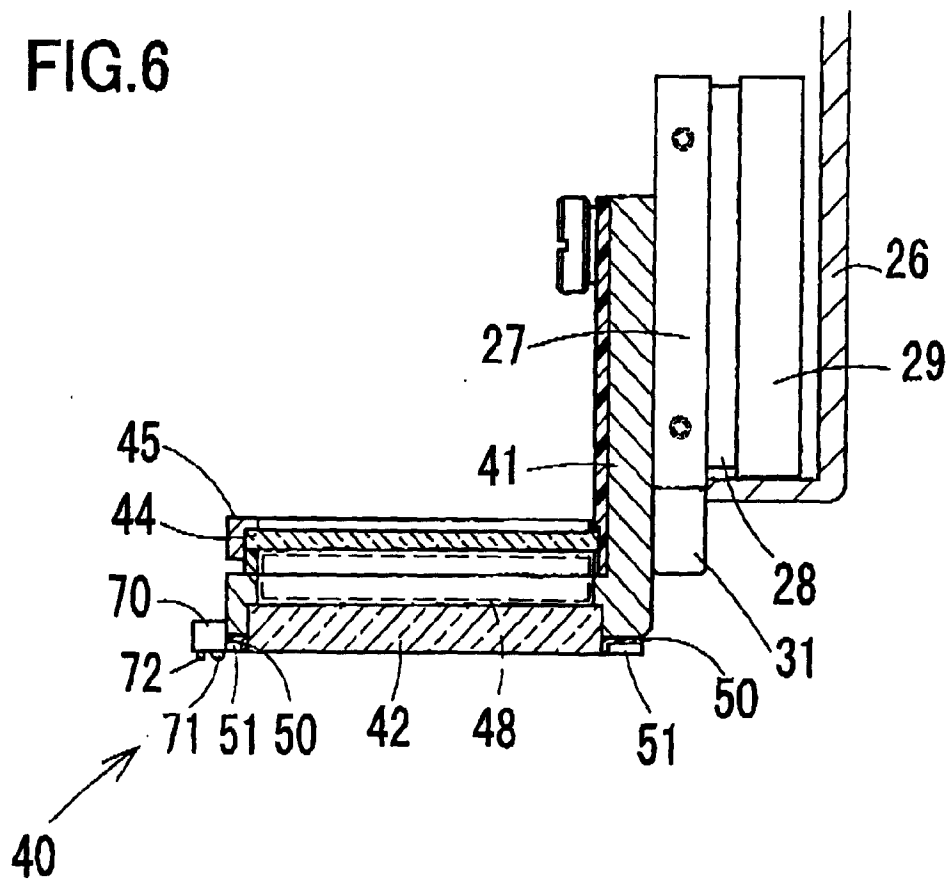


FIG.7A

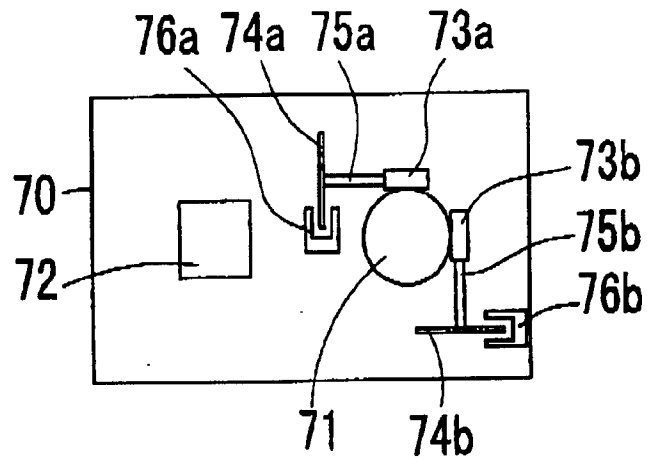


FIG.7B

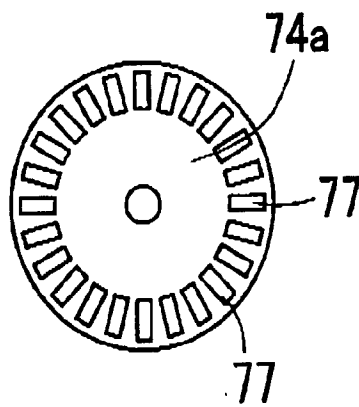


FIG.8

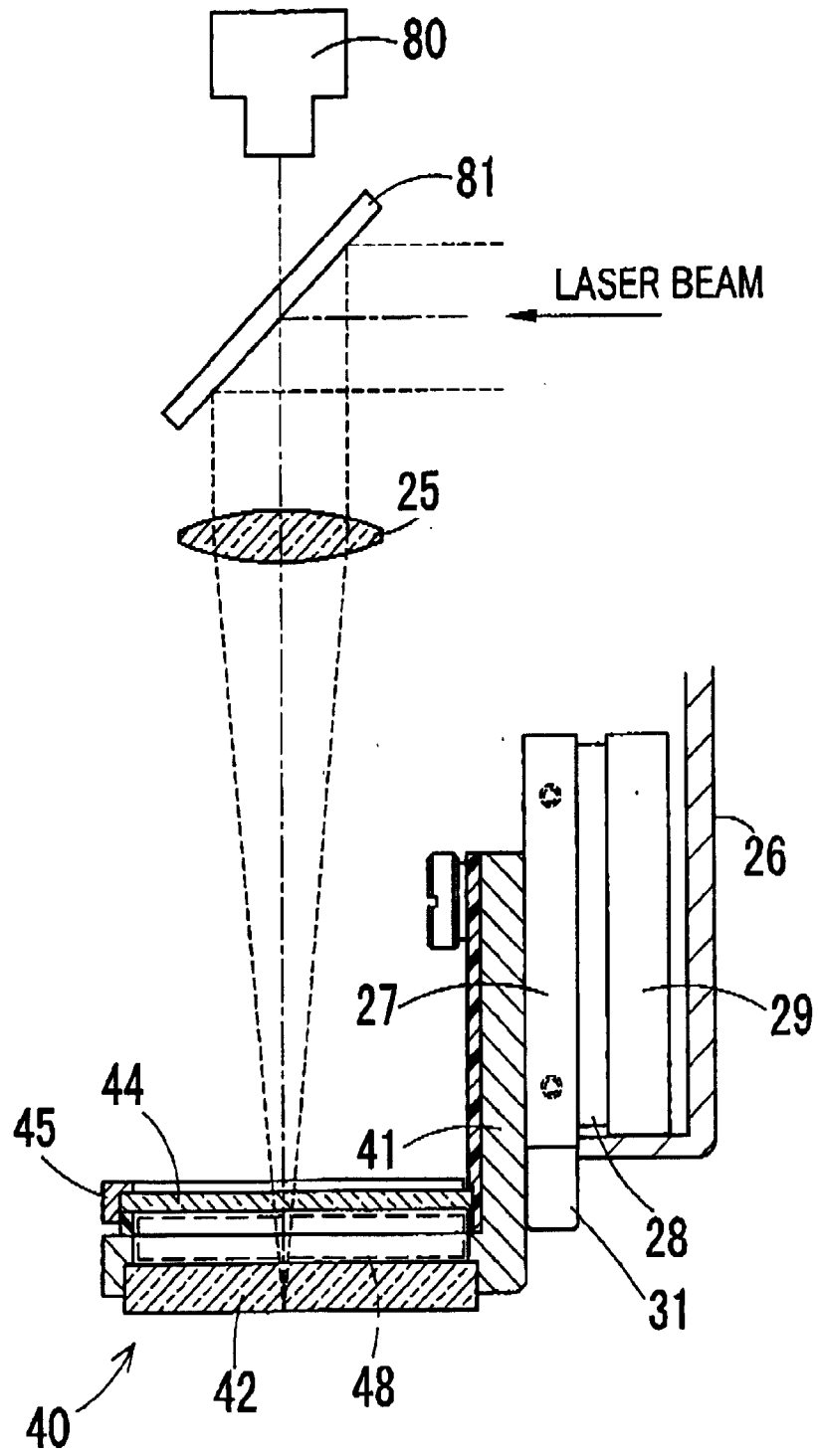
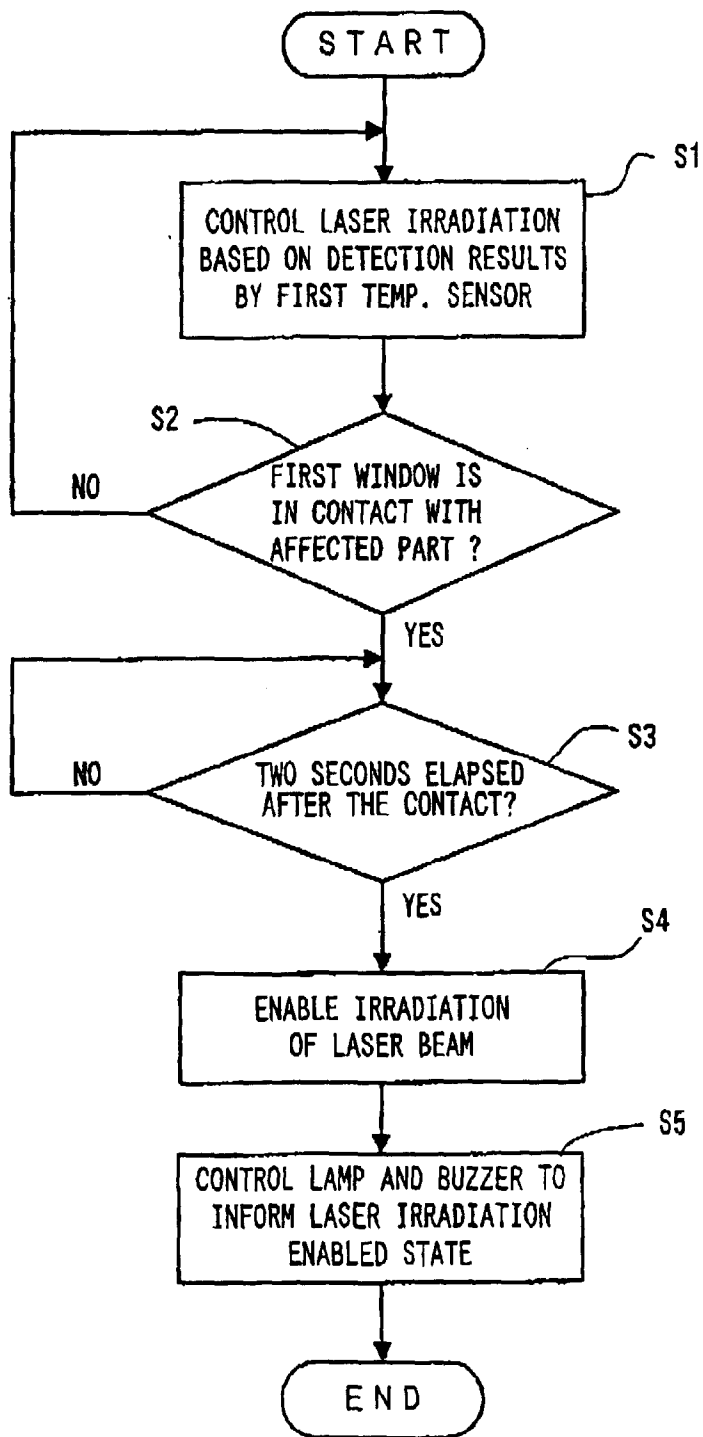


FIG. 9



(19)



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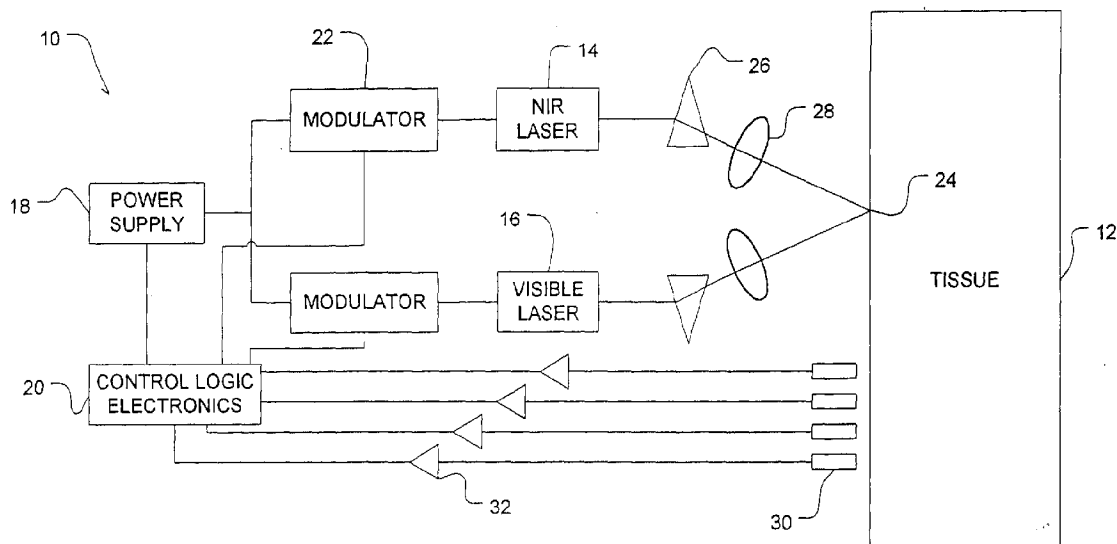
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**(54) Laser apparatus and method of use thereof**

(57) A method is provided for treating a patient having a disorder, wherein the method includes irradiating a tissue surface of the patient with at least one laser beam, automatically monitoring the tissue, and automatically controlling the at least one laser beam to adjust and/or terminate the treatment in a therapeutically effective manner. The method noninvasively determines

in real-time the irradiance and/or radiant exposure of a target tissue at a predetermined depth below the tissue surface by detecting the radial dependence of light remitted from the tissue surface. Preferably, the method employs a near-infrared light laser beam and a visible laser light beam in combination. An apparatus for performing the method is also provided.

**FIG. 1****EP 1 075 854 A2**

## Description

**[0001]** This invention relates to methods and devices for treating soft tissue disorders, and more particularly to laser therapeutic methods and devices.

**[0002]** Therapeutic lasers are useful in the treatment of certain types of tissue disorders. See, e.g. US Patents Nos. 4,215,694 to Isakov et al, 4,640,283 to Sawa et al, 4,671,285 to Walker, 4,724,835 to Liss et al, 4,930,504 to Diamantopoulos et al, 4,930,505 to Hatje, 4,966,144 to Rochkind et al, 5,092,581 to Kaga et al, 5,051,823 to Cooper et al, 5,150,704 to Tatebayashi et al, 5,320,619 to Badawi, 5,344,434 to Talmore, 5,409,482 to Diamantopoulos, 5,445,146 to Bellinger, 5,445,608 to Chen, 5,464,436 to Smith, 5,514,168 to Friedman, 5,616,140 to Prescott, 5,649,924 to Everett et al, 5,755,752 to Segal.

**[0003]** Laser therapy (i.e. Low Level Laser Therapy or LLLT) generally requires the injured tissue to be exposed directly to the laser light for predetermined intervals of time. Exposure to laser light not only lessens the pain associated with certain disorders, but actually speeds the healing of the treated tissues. The wavelength of the laser light, the intensity of the laser light and the exposure time are important factors when selecting a specific treatment protocol for a specific disorder.

**[0004]** The wavelength of the laser light affects its ability to penetrate through overlaying tissues, such as skin, to reach the tissues and molecules of interest. For example, red light is attenuated by most tissues ( $1/e^2$  attenuation), and thus the penetration depth is less than 1cm into such tissues, whereas near-infrared (NIR) light is less attenuated by most tissues, and thus can penetrate more than 1cm into such tissues.

**[0005]** The wavelength of the laser light also affects its ability to promote biological pathways for healing injured tissues. For example, the quantum energy of near-infrared photons is small, and thus near-infrared photons have a relatively low potential to electronically exciting biomolecules. On the other hand, the quantum energy of red wavelength photons is sufficient to achieve electronic excitation of biomolecules, potentially promoting direct photochemical and photobiological effects in target tissues.

**[0006]** The precise nature of the molecular events caused by narrow bandwidth red and near-infrared light irradiation is still under investigation. However, clinical evidence suggests that biostimulation using red light and biostimulation using near-infrared light each promotes wound healing and/or relieves the symptoms of rheumatoid arthritis. See, e.g. Mester et al, "Wound Healing", 1 Laser Therapy 7-15 (1989), and Asada et al, "Diode Laser Therapy for Rheumatoid Arthritis: A Clinical Evaluation of 102 Joints Treated with Low Reactive-Level Laser Therapy (LLLT) 1 Laser Therapy 147-152 (1989).

**[0007]** The intensity of the laser light used to treat an

injury is another factor in its effectiveness. Applying a therapeutically insufficient intensity of laser light to an injury has no desirable effects, but applying excess intensity can cause undesirable heating, burning and even vaporization of tissue.

**[0008]** The total exposure time is also an important factor in laser therapy, as combined with irradiance it determines the total deposited energy. If an injury is not exposed to laser light for an appropriate interval of time, insufficient healing may result. Excess exposure to laser light can injure the target tissues.

**[0009]** As the target tissue for laser therapy is typically subcutaneous, and the factors controlling the penetrability of a patient's skin (e.g. thickness, fat content, colour, etc.) vary from patient to patient, it has been difficult to employ one ideal protocol for all patients. That is, the target tissue is typically located at a certain depth " $Z_0$ " below the surface, and the energy delivered to depth " $Z_0$ " has been difficult to monitor and control. Protocols can be manually adjusted to the particular patient, but this adds complexity to the treatment, and more heavily relies on the proper training of medical personnel.

**[0010]** A variety of laser systems in the laser therapy and laser surgery arts have been proposed that intelligently control laser beam intensity and duration using target monitoring and feedback (real-time and otherwise). See, e.g. US Patents Nos. 5,657,760 to Ying, 5,423,801 to Marshall, 5,354,323 to Whitebook, 5,154,707 to Rink et al, 5,050,597 to Daikuzono, 4,973,848 to Kolobanov et al, and 4,644,948 to Lang et al.

**[0011]** According to one aspect of the invention there is provided a method for irradiating tissue with a near-infrared laser light having a first therapeutically effective intensity and with a visible laser light having a second therapeutically effective intensity; automatically monitoring said irradiated tissue; and automatically terminating said irradiating when said monitoring indicates that said near-infrared laser light and said visible laser light have been applied to said tissue for a duration therapeutically effective to treat said disorder.

**[0012]** According to another aspect of the invention, there is provided a laser apparatus adapted to perform the method of the invention, said laser apparatus comprising: a near-infrared light laser; a visible light laser; a power supply in electrical communication with said lasers; waveguides for guiding beams from said lasers to a common focal point on a surface of a target tissue; detectors adapted to detect radiation remitted from said target surface along a radius originating at said common focal point; and control logic electronics adapted to automatically adjust an output of said lasers based on said remitted radiation detected by said detectors.

**[0013]** The invention also provides a method for administering a predetermined dose of radiation to a distal target tissue, said method comprising: irradiating a proximal tissue adjacent said distal target tissue with at least one laser light which penetrates through said proximal

tissue to administer radiation to said distal target tissue; automatically monitoring said proximal tissue to determine whether to terminate said irradiating, said monitoring comprising detecting a radial dependence of a diffuse reflectance from a surface of said proximal tissue of said at least one laser light; and automatically terminating said irradiating when said monitoring indicates that said predetermined dose of laser light has been applied to said distal target tissue.

**[0014]** According to a still further aspect of the invention, there is provided a laser apparatus adapted to perform the method of the invention which comprises: at least one laser; a power supply in electrical communication with said at least one laser; at least one detector adapted to detect radiation remitted from two points on said target surface along a radius originating at a focal point of said at least one laser on said proximal tissue; and control logic electronics adapted to automatically adjust an output of said at least one laser based on said remitted radiation detected by said at least one detector.

**[0015]** The preferred apparatus of the invention is characterised by means for irradiating tissue with a near-infrared laser light having a first therapeutically effected intensity and with a visible laser light having a second therapeutically effected intensity; means for automatically monitoring said irradiated tissue and automatically terminating said irradiating when said monitoring means indicates that said near-infrared laser light and said visible laser light have been applied to said tissue in amounts therapeutically effective to treat said disorder.

**[0016]** The monitoring means preferably noninvasively determines the subsurface intensity of at least one of said near-infrared laser light and said visible laser light.

**[0017]** Preferably, said monitoring means analyzes a radial dependence of a diffuse reflectance from said tissue of at least one of said near-infrared laser light and said visible laser light. In the preferred embodiment, said diffuse reflectance is detected from at least two detection points on a surface of said tissue, said two detection points being at separate positions along a radius originating at a surface focal point of said laser lights.

**[0018]** The apparatus of the invention preferably also includes means for automatically adjusting the intensity of at least one of said near-infrared laser light and said visible laser light in response to information obtained by said monitoring means.

**[0019]** Preferably, the near-infrared laser light has a wavelength of 750 to 1000nm and the visible laser light has a wavelength of 450 to 749nm.

**[0020]** Preferably, the near-infrared laser light and the visible laser light has a peak intensity of 0 to 2000 watts/cm<sup>2</sup>.

**[0021]** The apparatus preferably also includes means to pulse the near-infrared laser light and said visible laser light. In the preferred embodiment, said means pulse the near-infrared laser light at a first frequency and said visible laser light at a second frequency different from

said first frequency, the signals of said near-infrared laser light and said visible laser light being detected by a common sensor and filtered by frequency.

**[0022]** Preferably, said irradiating is terminated when said monitoring means indicates that at least one of said near-infrared laser light and said visible laser light has penetrated to a sub-surface region of said tissue in an amount therapeutically effective to treat said disorder.

**[0023]** In a preferred apparatus for administering a predetermined dose of radiation to a distal target tissue, there are provided means for irradiating proximal tissue adjacent said distal target tissue with at least one laser light which penetrates through said proximal tissue to administer radiation to said distal target tissue; means for automatically monitoring said proximal tissue to determine whether to terminate said irradiating, monitoring means for detecting a radial dependence of a diffuse reflectance from a surface of said proximal tissue of said at least one laser light; and means for automatically terminating said irradiating when said monitoring indicates that said predetermined dose of laser light has been applied to said distal target tissue.

**[0024]** Preferably, said diffuse reflectance is detected from at least two detection points on said surface of said proximal tissue, said two detection points being at separate positions along a radius originating at a surface focal point of said at least one laser light.

**[0025]** Preferably, the apparatus also includes means for automatically adjusting the intensity of said at least one laser light.

**[0026]** Embodiments of the invention will now be described, by way of example only, with reference to the following drawings in which like reference numerals designate like elements and wherein:

Figure 1 is a schematic block diagram of an embodiment of the invention;

Figure 2 is a flow diagram of a process executed by the control logic electronics of the embodiment of Figure 1;

Figure 3 is a schematic block diagram of another embodiment of the invention; and

Figure 4 is a cross-sectional view through line 4-4 of Figure 3.

**[0027]** Figure 1 shows a general schematic diagram for a preferred laser apparatus 10 of the invention. Laser apparatus 10 is generally useful for treating, e.g. tissue disorders (as used herein, the expression "tissue disorders" denotes disorders associated with the tissues regardless of where such disorders originate or are manifested), such as tissue 12 shown in the figures. Laser apparatus 10 enables a method for treating tissue disorders to at least alleviate certain symptoms of the disorders, such as e.g. pain.

**[0028]** The laser apparatus 10 of Fig. 1 comprises one near-infrared (NIR) light laser 14 and one visible light laser 16. The lasers 14 and 16 are energized by a power

supply 18. The power output from power supply 18 is controlled by control logic electronics 20, either alone or in combination with modulators 22, as shown in the figures. Laser apparatus 10 is thereby adapted to control power density (i.e., irradiance in watts/cm<sup>2</sup>) delivered to the target tissue 12, as well as the total delivered energy dosage (i.e., radiant exposure in joules/cm<sup>2</sup>) of radiation.

**[0029]** In embodiments, laser apparatus 10 is adapted to selectively produce pulses of laser light at a frequency of between 0 to 50,000 and preferably 0 to 30,000 pulses per minute, each pulse preferably having a peak intensity of between 0 and 2000 watts/cm<sup>2</sup>.

**[0030]** NIR laser 14 is adapted to selectively produce laser light having a near-infrared wavelength and the frequency and intensity discussed above. Preferably, NIR laser 14 emits a beam having a wavelength of about 750 to about 1000 nm, more preferably about 900 to about 930 nm, most preferably about 905 nm.

**[0031]** Visible light laser 16 is adapted to selectively produce laser light having a wavelength in the visible light range and the frequency and intensity discussed above. Preferably, visible light laser 16 emits a beam having a wavelength of about 450 to about 749 nm, more preferably about 620 to about 670 nm, most preferably about 660 nm.

**[0032]** Lasers 14 and 16 can be the same or different types of laser, and in certain embodiments, lasers 14 and 16 can be merged into a single laser adapted to selectively produce coherent energy at wavelengths within the visible and near-infrared regions of the electromagnetic spectrum. Suitable lasers 14 and 16 according to the invention, include, e.g., noble gas lasers (e.g., argon lasers, helium-neon lasers, etc.), diode lasers and tunable dye lasers.

**[0033]** Each of the beams emitted from lasers 14 and 16 is preferably directed at a common focal point 24 on tissue 12, using a waveguide, such as a converging prism 26 and focusing lens 28, as shown in Fig. 1. Other suitable waveguides include, e.g., lenses having different configurations, a hollow metallic waveguide, a hollow dielectric waveguide, and/or an optical fiber (as discussed below and shown in Fig. 3). Suitable waveguides are also suggested in U.S. Patent No. 4,963,143 to Pinnow.

**[0034]** In embodiments, the laser beams converge prior to focal point 24, to yield coaxial beams comprising coherent radiation at a visible wavelength and coherent radiation at a near-infrared wavelength. The coaxial beams are preferable to other beam conformations, as the beams penetrate to subsurface regions directly below focal point 24, rather than subsurface regions that are not centered below focal point 24.

**[0035]** In embodiments wherein both beams are emitted by the same laser, the near-infrared beam and the visible beam can be alternately pulsed at focal point 24 to produce a desired effect.

**[0036]** Although dual wavelength laser irradiation is a

preferred embodiment of the invention, irradiation with a single wavelength or with more than two wavelengths of coherent radiation also forms a part of this invention, preferably in conjunction with the automated control system described immediately below.

**[0037]** In preferred embodiments, the invention includes an automated control system, comprising feedback-controlled irradiation of target tissues. A preferred laser apparatus according to the invention non-invasively detects, in real-time, the radiant exposure and/or irradiance of radiated energy within the tissue beneath the laser focal point on the surface of the target tissue. In particular, the diffuse reflectance of the visible and/or near-infrared light is detected, thus enabling the determination of the irradiance at a predetermined depth, and in conjunction with the exposure time, the actual radiant exposure at the predetermined depth.

**[0038]** Thus, detectors 30 are used to monitor the energy characteristics of tissue 12. Preferably, detectors 30 are positioned along a radius originating at focal point 24 to detect the diffuse radiation emitted from tissue 12. At least two detectors 30 are positioned at different points along the radius, and preferably four detectors 30 are so positioned, as shown in the figures. In embodiments, a single detector can be moved along a radius to measure the radial dependence of the diffuse radiation emitted from tissue 12. Detectors 30 suitable for use in the invention include, e.g., optical fibers terminating into fast silicon detectors, gallium arsenide detectors and indium phosphide detectors.

**[0039]** The signals from detectors 30 are preferably amplified by amplifiers 32 before being reported to control logic electronics 20.

**[0040]** Control logic electronics 20 include a processor (not shown), which executes modules 34-44 (Fig. 2). The processor in control logic electronics 20 detect (in module 34) when user activates a trigger, switch or button (not shown) of laser apparatus 10. When the trigger is depressed, the processor executes module 36 and then module 37. Until the trigger is depressed, the processor continues to execute module 34.

**[0041]** In module 36, control logic electronics 20 actuate lasers 14 and 16, and in module 37, control logic electronics 20 determine the intensity of the radiation at a predetermined depth,  $Z_0$ , within tissue 12 below focal point 24, and thus the radiant exposure and irradiance at  $Z_0$  with known exposure time. This determination is preferably made using an analysis of the radial dependence of diffuse remitted radiation detected by detectors 30 positioned along a radius originating at focal point 24.

**[0042]** The attenuation of the optical radiation from tissue 12 as a function of depth  $Z$  is related to the absorption and scattering properties of the tissue, resulting in large variations in the depth distribution of the power/energy. Using a theoretical model of light propagation in turbid media (e.g., tissue 12), such as Diffusion Theory, it can be shown that the radial dependence of the diffuse remitted radiation is also a function of the same optical



properties. See, e.g., Farrell et al., "A diffusion theory model of spatially resolved, steady-state diffuse reflectance for the non-invasive determination of tissue optical properties in vivo," 19(4) Med. Phys. 879-88 (1992), and Weersink et al., "Accuracy of non-invasive in vivo measurements of photosensitizer uptake based on a diffusion model of reflectance spectroscopy," 66(3) Photochem. Photobiol. 326-35 (1997). Hence, the radial dependence of the diffuse reflected radiation contains information regarding subsurface radiation.

**[0043]** Control logic electronics 20 determine the radial dependence of the diffuse reflected radiation from the intensity of the signal relayed to it from each detector 30, and the radial distance of each detector 30 from focal point 24. The radial dependence is then used to estimate the depth dependence of intensity (i.e., the attenuation of intensity as a function of depth) in the tissue being treated. For example, the radial dependence can be used to generate a curve or formula for a curve, which can in turn be used to select a depth dependence curve or formula from a look-up table. In any event, the intensity (or irradiance) of radiation at target depth  $Z_0$  is determined from the depth dependence curve or formula, and the radiant exposure at target depth  $Z_0$  is determined by, e.g., integration.

**[0044]** After executing module 37, the processor then executes module 38. In module 38, the processor compares the value of the radiant exposure at  $Z_0$  to a predetermined radiant exposure value. If the detected radiant exposure is greater than or equal to the predetermined radiant exposure value (which is preferably a therapeutically optimum value), module 40 is executed and lasers 14 and 16 are disabled. Lasers 14 and 16 can be disabled in a variety of ways, including interrupting the supply of power to them from power supply 18, modulating the power supply through modulators 22 to the lasers, and/or modulating the beam exiting lasers 14 and 16 using downstream laser modulators, such as shutters (not shown).

**[0045]** If the detected radiant exposure at  $Z_0$  is less than the predetermined radiant exposure, module 42 is executed. In module 42, the processor compares the value of the irradiance at  $Z_0$  with a predetermined irradiance (which is preferably a therapeutically optimum value). If the detected irradiance at  $Z_0$  is equal to the predetermined irradiance, module 37 is executed again. If the detected irradiance is not equal to the predetermined irradiance, module 44 is executed. Module 44 adjusts the intensity of the appropriate laser(s) in accordance with the discrepancy between the detected irradiance and the predetermined irradiance, and then executes module 37 again.

**[0046]** Control logic electronics 20 are preferably adapted to irradiate tissue 12 with radiation having a preselected peak intensity, average intensity and duration. Preferably, control logic electronics 20 are further provided with sufficient computer memory to store a series of treatment protocols for different ailments and/or

patients, eliminating the need to reprogram the device after each treatment.

**[0047]** Modulators 22 are included to provide the capability of modulating the output from lasers 14 and 16.

5 Modulation is preferably used for two purposes. First, modulation of laser output is used to control the radiant exposure and irradiance in tissue 12. Second, NIR laser 14 is preferably modulated at a different frequency than visible light laser 16 to enable frequency-filtered detection (e.g., using Fourier transform analysis). The remitted intensity of radiation having a first wavelength modulated by a first carrier frequency, can be distinguished from the remitted intensity of radiation having a second wavelength modulated by a second carrier frequency, by performing lock-in detection at the two different carry frequencies. The attenuation of the two respective wavelengths in the tissue of choice can be quantified by measuring the demodulation of the AC signal and the phase shift compared to the source. The intensity of the radiation emitted from tissue 12 can thus be determined at each of the two frequencies using common detectors.

**[0048]** Of course, other signal filtration systems are also suitable for use in the invention, including, e.g., optical filters and time-resolved filtration systems. Alternatively, a variety of narrow wavelength-specific detectors can be used in the apparatus of the invention to independently detect reflectance of a plurality of wavelengths.

**[0049]** Modulators 20 can be positioned before and/or after lasers 14 and 16. Suitable modulators 20 according to the invention include, e.g., frequency controlled driver circuits or acoustooptic modulators. Modulators 20 need not all be of the same type. For example, the modulators positioned before the lasers can be electrical devices adapted to control the amplitude and/or pulse timing of the laser beams emitted by the lasers, while the modulators after the lasers can be mechanical and/or optical shutters.

**[0050]** Fig. 3 shows an alternative embodiment of the invention, wherein focusing lenses 28 and optical fibers 46 act as waveguides directing the near-infrared laser beam and the visible laser beam through an applicator 48 and into tissue 12. This embodiment of the laser apparatus of the invention is particularly well-suited to treating tissue located in confined areas of the body, such as inside a body cavity, such as the mouth. Applicator 48 is applied to (or brought into close proximity with) tissue 12. Detectors 30 are preferably housed in applicator 48 for ease and precision of use.

**[0051]** In embodiments, applicator 48 is specifically adapted for its intended use. Interchangeable applicators 48 can be provided to customize the functionality of a universally adaptable (or at least widely adaptable) apparatus 10. Thus, for example, applicator 48 can be relatively small for conducting treatment within confined spaces, such as the mouth and endoscopic surgical fields. Applicator 48 can include "floating" detectors 30 and/or "floating" waveguide ends, which maintain close

contact between applicator 48 and tissue 12 despite surface irregularities of the tissue or tissue contours (in a manner similar to the spring-loaded laser heads disclosed in U.S. Patent No. 5,150,704 to Tatebayashi et al.).

**[0052]** Fig. 4 is a cross-sectional view through line 4-4 of Fig. 3, which demonstrates an example of the radial positioning of detectors 30 preferably used to determine the radial dependence of the diffuse reflected light.

**[0053]** In addition to targeting treatment to a single depth, the invention encompasses targeting treatment to a plurality of different depths within a tissue. The multiple depth treatments of the invention can be administered simultaneously, sequentially and/or alternately. For example, a system of the invention can be adapted to target a first depth, reset to target a second depth, reset again to target a third depth, and so forth. In conjunction with the ability of systems of the invention to adjust irradiance, radiant exposure, and wavelength, the ability to target multiple depths provides systems of the invention with superior adaptability to a variety of disorders of a variety of tissues in a variety of patients.

**[0054]** The invention is additionally suitable for monitoring and controlling thermal laser applications, using feedback from the tissue to control laser dosage.

**[0055]** The invention will be illustrated in more detail with reference to the following Example, but it should be understood that the present invention is not deemed to be limited thereto.

#### Example

**[0056]** A forearm of a patient complaining of pain and stiffness associated with carpal tunnel syndrome is treated with laser beams having wavelengths of 660 nm and 905 nm simultaneously. A laser treatment apparatus of the invention is used to automatically monitor and control the application of the laser light to apply the irradiance and radiant exposure so that a predetermined fluence-rate and fluence are achieved at depth Z. The apparatus is actuated and the diffuse reflectance of the laser light is detected at several points along a radius originating at the focal point of the laser light on the tissue surface.

**[0057]** To correlate the reflectance as a function of radius  $R(\rho)$  with the fluence-rate as a function of depth  $\phi(Z)$ , a look-up table is generated using diffusion theory (see Farrell et al., supra). For the look-up table, the reflectance,  $R$ , at the position of the detectors ( $\rho_{x1} \rightarrow \rho_{xn}$ ) and the fluence-rate at depth ( $Z_1 \rightarrow Z_n$ ) are calculated for the full range of optical absorption and scattering at 660 nm and 905 nm wavelengths, as reported in the literature for human skin.

**[0058]** In the look-up table, the shape of the reflectance vs. radius @ vs.  $\rho_x$ ) curve is used to select the corresponding fluence-rate vs. depth ( $\phi$  vs.  $Z$ ) curve. The fluence-rate at depth  $Z$  (the parameter of interest) is then obtained through interpolation of the data of  $\phi$  vs.  $Z$ .

**[0059]** The irradiance delivered by the apparatus is adjusted to achieve the predetermined  $\phi(Z)$ . The adjustment can be limited by reference to predetermined safety limits, such as those published in IEC 825-1, at Table 8 (MPE for skin at 905 nm is about 500 mW and at 660 nm it is about 200 mW).

**[0060]** While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

#### Claims

1. A laser apparatus **characterised by** a near-infrared light laser; a visible light laser; a power supply in electrical communication with said lasers; waveguides for guiding beams from said lasers to a common focal point on a surface of a target tissue; detectors adapted to detect radiation remitted from said target surface along a radius originating at said common focal point; and control logic electronics to automatically adjust an output of said lasers based on said remitted radiation detected by said detectors.
2. A method of irradiating tissue characterised by the steps of: irradiating said tissue with a near-infrared laser light having a first therapeutically effective intensity and with a visible laser light having a second therapeutically effective intensity; automatically monitoring said irradiated tissue; and automatically terminating said irradiating when said monitoring indicates that said near-infrared laser light and said visible laser light have been applied to said tissue in amounts therapeutically effective to treat said disorder.
3. The method of claim 2 characterised in that said monitoring comprises noninvasively determining subsurface intensity of at least one of said near-infrared laser light and said visible laser light.
4. The method of claim 3 characterised in that said noninvasive determination comprises analyzing a radial dependence of a diffuse reflectance from said tissue of at least one of said near-infrared laser light and said visible laser light.
5. The method of claim 4 characterised in that said diffuse reflectance is detected from at least two detection points on a surface of said tissue, and wherein said two detection points are at separate positions along a radius originating at a surface focal point of said laser lights.
6. The method of any of claims 2-5 characterised by

automatically adjusting an intensity of at least one of said near-infrared laser light and said visible laser light in response to information obtained by said monitoring.

7. The method of any of claims 2-6 characterised in that said tissue comprises musculo-skeletal soft-tissue.

8. The method of any of claims 2-7 characterised in that said near-infrared laser light has a wavelength of 750 to 1000nm.

9. The method of any of claims 2-8 characterised in that said visible laser light has a wavelength of 450 to 749nm.

10. The method of any of claims 2-9 characterised in that said near-infrared laser light has a peak intensity of 0 to 2000 watts/cm<sup>2</sup>.

11. The method of any of claims 2-10 characterised in that said visible laser light has a peak intensity of 0 to 2000 watts/cm<sup>2</sup>.

12. The method of any of claims 2-11 characterised in that said near-infrared laser light and said visible laser light are pulsed.

13. The method of any of claims 2-12 characterised in that said near-infrared laser light is pulsed at a first frequency and said visible laser light is pulsed at a second frequency different from said first frequency, and wherein signals of said near-infrared laser light and said visible laser light are detected by a common sensor and filtered by frequency.

14. The method of any of claims 2-13 characterised in that said irradiating is terminated when said monitoring indicates that at least one of said near-infrared laser light and said visible laser light has penetrated to a sub-surface region of said tissue in an amount therapeutically effective to treat said disorder.

15. A method for administering a predetermined dose of radiation to a distal target tissue characterised by the steps of: irradiating a proximal tissue adjacent said distal target tissue with at least one laser light which penetrates through said proximal tissue to administer radiation to said distal target tissue; automatically monitoring said proximal tissue to determine whether to terminate said irradiating, said monitoring comprising detecting a radial dependence of a diffuse reflectance from a surface of said proximal tissue of said at least one laser light; and automatically terminating said irradiating when said monitoring indicates that said predetermined dose

of laser light has been applied to said distal target tissue.

16. The method of claim 15 characterised in that said diffuse reflectance is detected from at least two detection points on said surface of said proximal tissue, and wherein said two detection points are at separate positions along a radius originating at a surface focal point of said at least one laser light.

17. The method of claim 15 or claim 16 characterised by automatically adjusting an intensity of said at least one laser light.

18. The method of any of claims 15-17 characterised in that said predetermined dose is an amount therapeutically effective to treat a disorder.

19. A laser apparatus adapted to perform the method of claim 15 characterised by at least one laser; a power supply in electrical communication with said at least one laser; at least one detector adapted to detect radiation remitted from two points on said target surface along a radius originating at a focal point of said at least one laser on said proximal tissue; and control logic electronics adapted to automatically adjust an output of said at least one laser based on said remitted radiation detected by said at least one detector.

FIG. 1

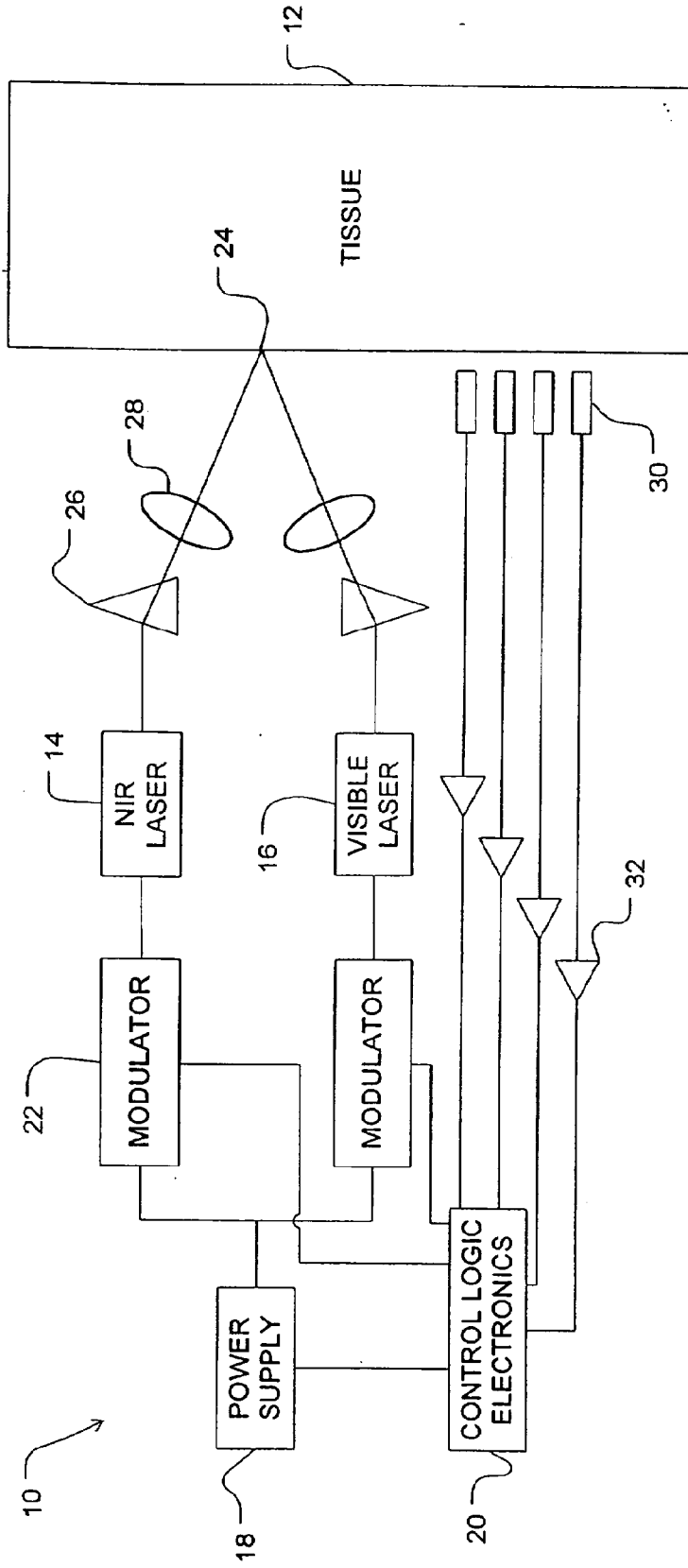


FIG. 2

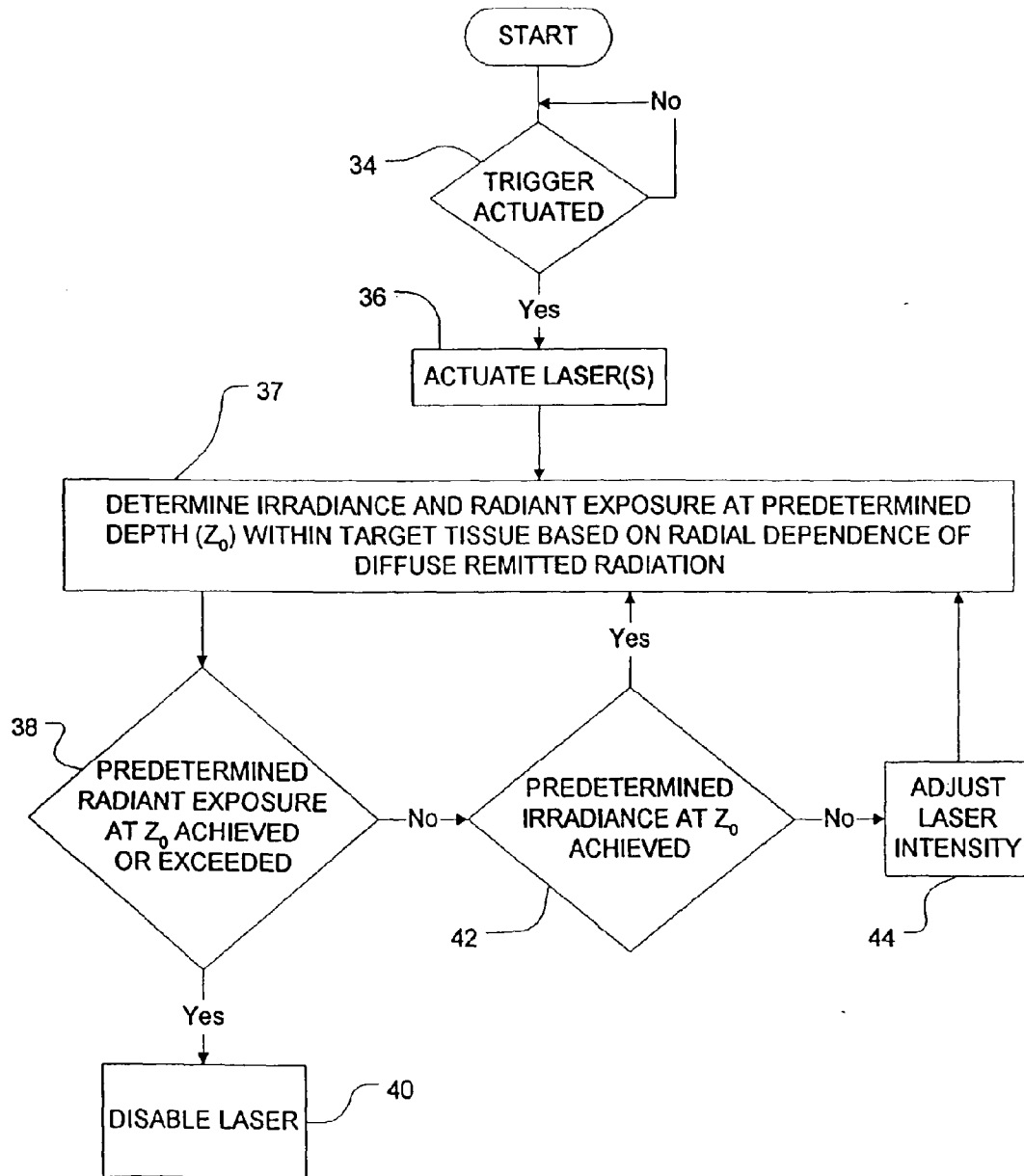


FIG. 3

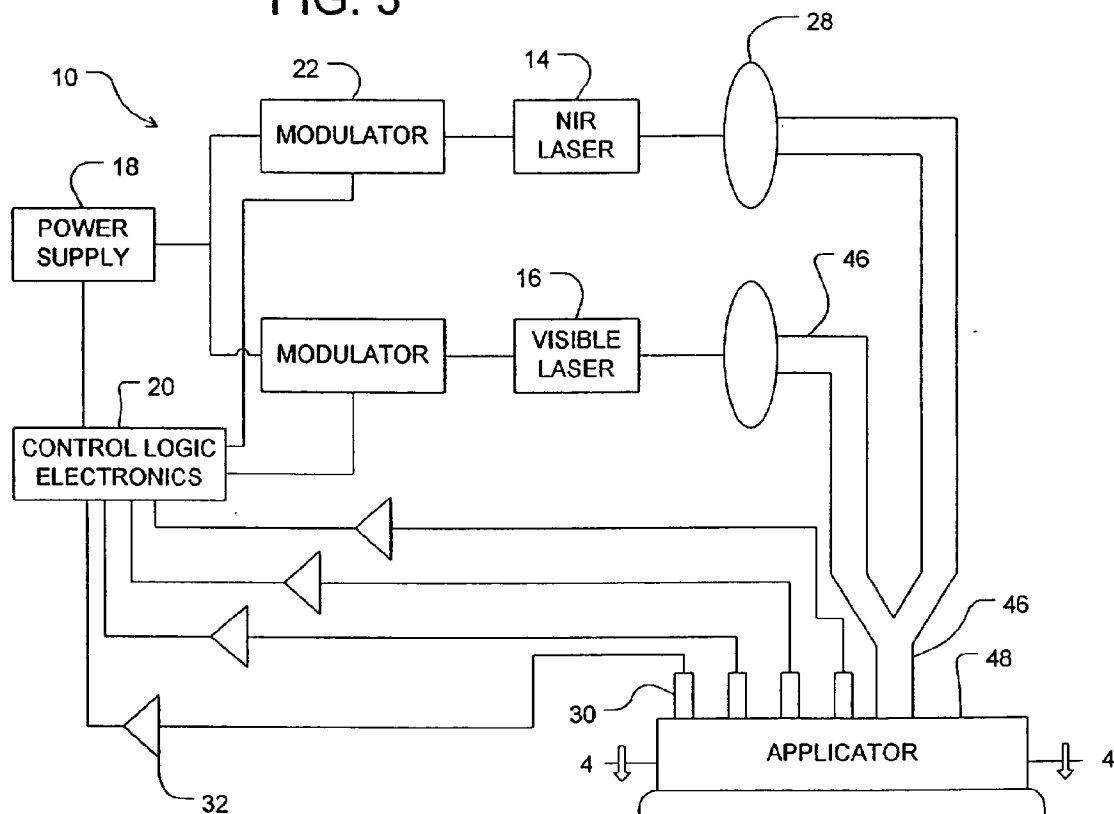
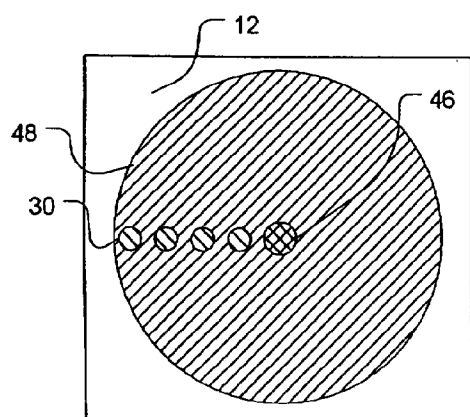


FIG. 4





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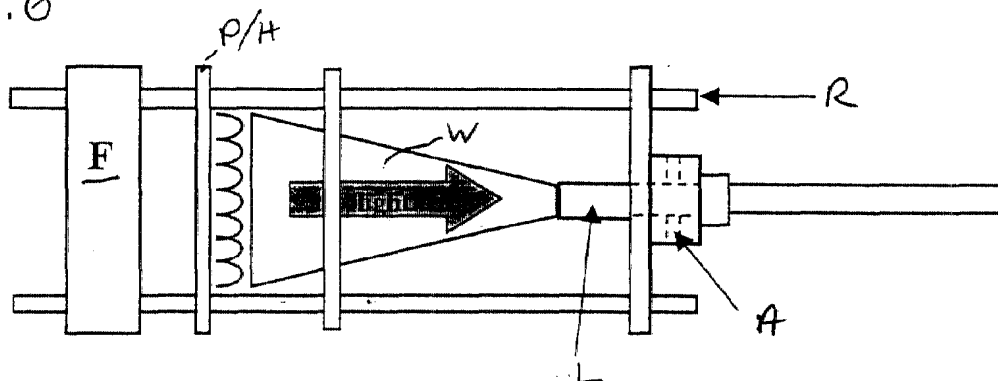
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(54) **Therapeutic light source**

(57) A therapeutic light source, for example for photodynamic therapy (PDT), comprises an air-cooled array of LED's ( $L_{x,y}$ ), the air being vented in the vicinity of the array. The array may be mounted at the distal end of a hand piece suitable for invasive therapy. The LED's may be coupled to a light guide (W, L). The emission spectra of the LED's may be substantially limited to the range 550 to 660 nm, and preferably to one of the ranges

590 to 640 nm, 560 to 644 nm, 650 to 660 nm, and 550 to 570 nm. The therapeutic light source may comprise a non-planar array of light-emitting diodes L conforming with the shape of an external area to be treated or diagnosed. The therapeutic light source may comprise a non-planar array of independently switchable red and blue light-emitting diodes  $L_R$ ,  $L_B$ , mounted on a flexible backing.

Fig. 6



**Description**

**[0001]** The present invention relates to a non-coherent light source for use in therapy such as photodynamic therapy (PDT), particularly using light emitting diodes (LED's).

**[0002]** Photodynamic therapy involves the administration of a photosensitising drug to an affected area, and its subsequent irradiation with light - see for example 'The Physics of Photodynamic Therapy' by B C Wilson and M S Patterson, Physics in Medicine & Biology 31 (1986) April No. 4, London GB.

**[0003]** The document GB 2,212,010 discloses a therapeutic light source which uses an array of discrete LED's as an alternative to lasers or laser diodes. The output of the LED's is focussed so as to provide the necessary intensity.

**[0004]** The document WO 94/15666 discloses a therapeutic light source specifically for PDT, with an integrated array of LED's mounted on the distal end of a hand piece. The LED's are overdriven to give the necessary intensity, and cooled by the flow of water around a closed loop passing along the hand piece. The document US 5728090 discloses a somewhat similar device with various different types of head containing integrated LED matrices. These devices require complicated liquid cooling circuits which would add to the cost of the device and add to the bulk of the hand piece, which is disadvantageous for invasive use.

**[0005]** The document US 5728090 mentions that the wavelength of the LED's is between 300 nm and 1300 nm and is selected based upon the particular photosensitive dye used during PDT. However, the wavelengths of LED's capable of providing the necessary intensity for PDT cannot freely be chosen within that range.

**[0006]** According to one aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a non-planar array of light-emitting diodes conforming with the shape of an external area to be treated or diagnosed.

**[0007]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.

**[0008]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.

**[0009]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.

**[0010]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.

**[0011]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on the surface thereof an array of discrete light-emitting diodes.

**[0012]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an air-cooled array of LED's, the air being vented in the vicinity of the array. In one embodiment, the array is mounted at the distal end of a hand piece suitable for invasive therapy.

**[0013]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's coupled to a light guide for delivering the light to the area to be treated. Preferably, the LED's are directly coupled without intervening optical devices.

**[0014]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with emission spectra substantially limited to the range 550 to 660 nm, and preferably to one of the ranges 590 to 640 nm, 560 to 644 nm, 650 to 660 nm, and 550 to 570 nm.

**[0015]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm, 470 nm, 505 nm or 525 nm.

**[0016]** Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a diagram of a parallel-series matrix of discrete LED's used in first and second embodiments of the present invention;

Figure 2 is perspective diagram of the first embodiment;

Figure 3 is a cross section of part of the first embodiment;

Figure 4 is a graph showing the variation of intensity in a cross-section of the output of the first embodiment;

Figure 5 is a cross-sectional diagram of a second embodiment;

Figure 6 is a cross-sectional diagram of a third embodiment;

Figure 7 is a cross-sectional diagram of a fourth embodiment;



Figure 8 is a cross-sectional diagram of a fifth embodiment;

Figure 9 is a graph showing the absorption spectrum of PpIX and the emission spectra of two examples of LED's suitable for use with the embodiments;

Figures 10a and 10b are side and front views respectively of an LED array in a sixth embodiment for treatment of the face;

Figures 11a, 11b and 11c are a cross-section in the plane of the patient's arm, a top view and a vertical cross-section transverse to the patient's arm of an LED array in a seventh embodiment for treatment of the elbows of a patient;

Figure 12 is a side view of an LED array in an eighth embodiment used for treatment of the foot or feet;

Figure 13 is a side view of an LED array in a ninth embodiment used for treatment of the lower leg;

Figures 14 and 15 show arrangements of an LED array in tenth and eleventh embodiments for treatment of respectively the face and a section of a patient lying on a bed;

Figures 16a and 16b show respectively front and side views of a set of similar LED arrays in a twelfth embodiment for treatment of one side of a patient;

Figures 17a and 17b show respectively front and side views of an LED array in a thirteenth embodiment for treatment of a section of one side of a patient;

Figures 18a and 18b are respectively side and end views of a set of similar LED arrays in a fourteenth embodiment, for treatment of one side of a patient lying down;

Figures 19a and 19b are respectively side and end views of an LED array in a fifteenth embodiment for treatment of a section of a patient lying down;

Figures 20a and 20b are top and side views respectively of an arrangement of LED arrays in a sixteenth embodiment for treatment of the face and/or scalp;

Figure 21 shows a similar arrangement to that of Figures 20a and 20b, in a seventeenth embodiment for treatment of the face and/or scalp of a patient lying down;

Figures 22a, 22b and 22c show respectively a side view, a transverse cross-section and a longitudinal cross-section of an LED array arranged within a sleeve in an eighteenth embodiment, for treatment of the hand, forearm and/or elbow;

Figures 23a, 23b and 23c show respectively two different shapes of flexible LED array, and a flexible array applied as a patch onto the skin of a patient, in a nineteenth embodiment;

Figure 24 shows an LED array arranged on the side of a cylindrical intraluminal probe in a twentieth embodiment;

Figure 25 shows an LED array arranged on the surface of a spherical intraluminal probe in a twenty-first embodiment; and

Figure 26 shows a more specific example of the flexible LED array in the nineteenth embodiment.

**[0017]** In a therapeutic light source in the first embodiment, as illustrated in Figures 1 to 5, light is emitted from a parallel-series matrix of LED's L connected through a current-limiting resistor R to a source of a voltage +V. The LED matrix is mounted on a heatsink array H parallel to and spaced apart from a fan array F by support rods R. Air is blown by the fan array F onto the back of the heatsink array H.

**[0018]** As shown in more detail in Figure 3, the heatsink array H comprises a plurality of individual heatsinks h mounted on the ends of the legs of the LED's, which pass through a support plate P. Each leg is soldered to an adjacent leg of another of the LED's in the same column. The support plate P is perforated to allow air to flow more freely around the heatsinks h and the LED's L.

**[0019]** The LED's L are arranged so as to produce a substantially uniform illumination of  $\pm 10\%$  or less across a treatment field by selecting the beam divergence and spacing of the LED's L so that their individual beams overlap without causing substantial peaks or troughs in intensity. In the example shown in Figure 4, uniformity of  $\pm 6\%$  is achieved. In this embodiment, no optical system is needed between the LED's and the patient; instead, the light is emitted directly from the LED's onto the patient. As the light is not concentrated by any optical system, the LED's have individual power outputs of at least 5 mW and preferably at least 10 mW, to give the necessary fluence rates in the treatment field of at least 30 mW/cm<sup>2</sup> in the red region of the spectrum and at least 10 mW/cm<sup>2</sup> in the blue region.

**[0020]** In one specific example, a 15 cm diameter array of 288 'Super flux' LED's was used to produce a total light output of 8 W at 45 mW/cm<sup>2</sup> in the treatment field. The LED's were driven at a higher current load than their specification while being cooled by forced air convection from the fans F. In the specific example, the current was limited to 90 mA per column of diodes, but may be increased to 120 mA or more if increased light output is needed. The number of diodes in series, in each column, is selected so that the total forward operating voltage is as close as possible to, but less than, the power supply output voltage, in this case 48 V. This arrangement avoids wasteful in-circuit heating and maximizes the operating efficiency of the electrical system.

**[0021]** A method of treatment for oncological and non-oncological skin diseases such as cases of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis

fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism, using the first embodiment, will now be described. A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected area of the skin of the patient, or administered intravenously or orally. In another method of application for large areas, the patient may be immersed in a bath of solution. The affected area may then be covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is then uncovered and exposed to light from the lamp according to the first embodiment for a period of 15 to 30 minutes. The treatment may then be repeated as necessary, for a total of 1 to 3 treatments. This method is particularly suitable for the treatment of patients with very large lesions or multiple lesions extending over a large area.

**[0022]** In a method of treatment using the device of the first embodiment, the LED array is positioned approximately parallel to an external affected area of a patient to be treated, with a separation sufficient to achieve the uniform illumination as shown in Figure 4, for example 2 to 5 cm. The device may also be used for cosmetic or partially cosmetic treatment with a photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

**[0023]** The lamp may also be used for fluorescence detection (photodiagnosis).

**[0024]** The first embodiment may be modified in a second embodiment, as shown in Figure 5, by the addition of a frusto-conical waveguide W, for example of acrylic (e.g. Perspex™) or glass, supported by the support rods R, which are extended in this embodiment. The waveguide W is arranged to concentrate light emitted by the LED's onto a smaller area with higher intensity. This arrangement is suitable for treating smaller external surfaces.

**[0025]** The second embodiment may be modified in a third embodiment, as shown in Figure 6, to deliver the light from the waveguide W into a lightguide L for internal treatment. The lightguide L, such as an optical fibre or fibre bundle, or liquid light guide, is held in a lightguide receptacle or adapter A, that is compatible for example with Olympus, Storz, ACMI or Wolf light cable fittings, in abutment or immediately adjacent relation with the narrow end of the waveguide W. The lightguide L may be of 3, 5 or 8 mm diameter. The support rods R align the optical axes of the waveguide W and lightguide L, so that the light emitted by the waveguide W is launched into the lightguide L. In the third embodiment, the light is concentrated by the waveguide and emitted over a small area at the distal end of the lightguide L which may be inserted into body cavities for oral, gynaecological, gastrointestinal or intraluminal treatment.

**[0026]** The third embodiment may be modified in a fourth embodiment, as shown in Figure 7, in which the discrete LED array is replaced by an integrated multi-die LED matrix IM (for example part no. OD 6380, OD 6624 or OD 6680 available from AMS Optotech, Bristol, UK) mounted on the support plate/heatsink P. H. A Peltier effect thermoelectric cooler PC is mounted in thermal contact with the opposite side of the support plate P, the heated side of which is cooled by the fan F. The proximal end of the lightguide L is directly adjacent or abutting the integrated LED matrix IM, which are of similar cross-section so that the waveguide is not needed to launch the emitted light into the lightguide L.

**[0027]** A fifth embodiment, as shown in Figure 8, is designed specifically for treatment of the cervix, such as PDT treatment. The fifth embodiment has the form of a hand piece having a hollow stem S, for example of acrylic or polycarbonate, through which air is blown at low pressure by a fan F mounted at the proximal end. The distal end has a head portion HP comprising a housing within which is mounted a discrete LED array mounted on a support plate/heatsink P/H. Air passes through the hollow stem S onto the heatsink H so as to extract heat therefrom and is then vented through apertures AP on the proximal side of the housing. The distal end of the housing is concave and dimensioned so as to fit closely over the end of the cervix C. A transparent end window W, for example of acrylic or glass, prevents infiltration of the LED's. Power is carried to the LED's through wires (not shown) mounted on the wall of the acrylic stem S. In use, the hand piece is positioned so that the distal end fits over the cervix of the patient and is clamped in position for the duration of the treatment.

**[0028]** The selection of appropriate discrete LED's for PDT using any of the first to fourth embodiments will now be described, grouped according to die material.

**[0029]** A first suitable type of LED is based on aluminium indium gallium phosphide/gallium phosphide (AlInGaP/GaP) of transparent substrate (TS) or absorbing substrate (AS) type. The output wavelengths are in the range 590 to 640 nm with peak emission wavelengths of 590, 596, 605, 615, 626, 630 and 640 nm. Commercially available examples are the 'SunPower'™ or 'Precision Optical Power'™ series from Hewlett Packard Company, designed for use in the automotive industry, for commercial outdoor advertising and traffic management. Suitable LED's are those packaged as: SMT (surface mount technology) e.g. HSMA, HSMB, HSMC, HSML series and preferably HSMB HR00 R1T20 or HSMB HA00R1T2H; Axial e.g. HLMA or HLMT series; T1 e.g. HLMP series, preferably HLMP NG05, HLMP NG07, HLMP J105; T13/4 e.g. HLMP series, preferably HLMP DG08, HLMP DG15, HLMP GG08, HLMP DD16; Superflux™ e.g. HPWA or HPWT series, preferably HPWA (MH/DH/ML/DL) 00 00000, HPWT (RD/MD/DD/BD/RH/MH/DH/BH/RL/ML/DL/BL) 00 00000, most preferably HPWT (DD/DH/DL/MH/ML/MD) 00 00000; SnapLED™ e.g. HPWT, HPWS, HP-

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WL series, preferably HPWT (SH/PH/SL/PL) 00, HPWT (TH/FH/TL/FL) 00 or HPWS (TH/FH/TL/FL) 00. Suitable products from other manufacturers include: of SMT type, Advanced Products Inc. (API) part no. HCL4205AO; of T1 type, American Bright Optoelectronics (ABO) part no. BL BJ3331E or BL BJ2331E; of Superflux type, ABO part no.'s BL F2J23, BL F2J33 and BL F1F33.

**[0030]** A second suitable type of LED is the aluminium indium gallium phosphide/gallium arsenic (AlInGaP/GaAs) type, with emission wavelengths in the range 560 to 644 nm and peak emission wavelengths of 562 nm, 574 nm, 590 nm, 612 nm, 620 nm, 623 nm and 644 nm. Examples commercially available from Toshiba in T1 package are the TLRH, TLRE, TLSH, TLOH or TLYH series, preferably TLRH 262, TLRH 160, TLRE 160, TLSH 1100, TLOH 1100, TLYH 1100 or S4F4 2Q1; or in T13/4 package are the TLRH or TLSH series, preferably TLRH 180P or TLSH 180P. Another example is Kingbright L934SURC-E.

**[0031]** A third suitable type of LED is aluminium gallium arsenic type (AlGaAs), with emission wavelengths in the range 650 to 660 nm. Examples in T1 package include the Toshiba TLRA series, preferably TLRA 290P or TLRA 293P, and Kingbright L934 SRCG, L934 SRCH, and L934 SRCJ and in T13/4 package include Kingbright L53 SRCE.

**[0032]** A fourth suitable type of LED is gallium phosphide (GaP) type, with emission wavelengths in the range 550 to 570 nm.

**[0033]** A fifth suitable type of LED is indium gallium nitride (InGaN). In the type with an emission wavelength of 525 nm, commercially available examples include: in SMT package, API's HCL 1513AG; and in T1 package, Farnell's #942 467, Radio Spare's #228 1879 and #249 8752, API's HB3h 443AG and Plus Opto's NSPG500S. In the type with emission wavelengths of 470 and 505 nm and T1 package type, examples are Farnell's #142 773, Radio Spare's #235 9900 and American Bright Optoelectronics Inc.'s BL BH3PW1.

**[0034]** A sixth suitable type of LED is gallium nitride/silicon (GaN/Si), with an emission wavelength of 430 nm. One commercial example is Siemens LB3336 (also known as RS #284 1386).

**[0035]** Each of the above LED types is selected to have an emission spectrum substantially coincident with the absorption spectrum of one or more of the following common photosensitizers given below in Table 1, and therefore embodiments having such LED's are suitable for PDT. For example, Figure 9 shows the absorption spectrum of PpIX, including peaks at 505nm, 545 nm, 580 nm and 633 nm. Inset are the emission spectra, in units of peak intensity and on the same wavelength axis, of LED part no. HPWA DL00 with a peak at 590 nm and LED part no. HPWT DH00 with a peak at 630 nm, the peaks having sufficient breadth to give a substantial overlap with the 580 nm and 633 nm peaks respectively in the absorption spectrum of PpIX.

Table 1

Photosensitizer	Red absorption Band (nm)	Red Peak (nm)	Blue/Green Peak (nm)
Naphthalocyanines	780-810		
Chalcogenopyrillium dyes	780-820		
Phthalocyanines (e.g. ZnII Pc)	670-720	690	
Tin etiopurpurin (SnET <sub>2</sub> )	660-710	660-665	447
Chlorins (e.g. N-Aspartyl chlorin e6 or NPe6)	660-700	664	
Benzoporphyrin derivative (BPD)		685/690	456
Lutetium texaphrin (Lu-TeX)		735	
Al(S <sub>1</sub> /S <sub>2</sub> /S <sub>3</sub> /S <sub>4</sub> ) Pc	660-710	670/685	410, 480
Photofrin		625/630	405
Protoporphyrin IX (PpIX) - from 5/δAminolaevulinic Acid (5ALA)		635	410, 505, 540, 580
Tetra m-hydroxyphenyl Chlorin (mTHPC)		650	440, 525

**[0036]** The discrete LED array may comprise more than one different type of LED, each with different emission spectra, selected to match different absorption bands of the selected photosensitizer. Each type of LED may be switched independently. The penetration depth (i.e. the depth at which the intensity has been attenuated to e<sup>-1</sup>) may also be varied by switching on only one type of LED in the array so as to select a suitable emission band, since the penetration

depth is a function of the wavelength.

**[0037]** The LED array may be composed of individually switchable spatially distinct segments of LED's. Selected segments may be switched on so as to treat a selected area of the patient within the overall area of the matrix array.

**[0038]** The lamp may include an electro-optical detector arranged to monitor the light dose delivered and to switch off the light emission when a target dose is reached. Alternatively, or additionally, the detector is arranged to monitor the instantaneous light intensity and to vary the electrical power supplied to the tubes so as to maintain the intensity within predetermined limits, and/or to switch off the light emission if a maximum limit is exceeded.

**[0039]** Various different arrangements of LED array suitable for treatment of different areas of a patient will now be described. The LED's are discrete LED's as described above. Except where stated otherwise, the LED's may be fan-cooled using integrated fans.

**[0040]** Figures 10a and 10b show an array of LED's L in a sixth embodiment, arranged on a support P shaped as a curved visor for treatment of the face of a patient. The array is supported in front of the patient's face by a head band HB or other head wear worn by the patient.

**[0041]** Figures 11a to 11c show an array of LED's L in a seventh embodiment arranged within a cuboid housing HO which has two similar apertures AP on one face, to allow the elbows to be inserted into the housing HO. The edges of the apertures AP are cushioned to allow the arms to be rested comfortably. Within the housing HO is arranged a surface SU which is curved both in the plane of the arms and perpendicular to that plane, as shown in Figure 11c. The LED's L are mounted on this surface SU so that light emitted therefrom is concentrated onto the elbows of the patient.

**[0042]** Figure 12 shows an LED array L in an eighth embodiment mounted on a support plate P, and covered by a transparent or translucent cover on which the foot or feet of the patient rest during treatment.

**[0043]** Figure 13 shows an LED array L in a ninth embodiment mounted on a support plate P and arranged for treatment of the lower leg of a patient.

**[0044]** Figures 14 and 15 show an LED array L, mounted in a housing HO in the form of a trapezoid prism, the upper inner surface carrying the LED array and the lower surface being open to allow light to fall onto the patient. The side faces may be reflective, or carry additional LED arrays. In the tenth embodiment shown in Figure 14, the housing HO is mounted at one end of a bed so that its height above the bed is adjustable, for facial treatment of a patient lying on the bed. In the eleventh embodiment shown in Figure 15, the housing HO is mounted on a stand ST and is adjustable in height, for treatment of a selected part of a patient lying on the bed.

**[0045]** Figures 16a and 16b show a series of four coplanar LED arrays L in a twelfth embodiment arranged to treat one side of a patient. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

**[0046]** Figures 17a and 17b show a single LED array L in a thirteenth embodiment positioned to treat a section of the patient.

**[0047]** Figures 18a and 18b show a series of three coplanar LED arrays L in a fourteenth embodiment arranged to treat one side of a patient lying down. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

**[0048]** Figures 19a and 19b show an array of LED's L in a fifteenth embodiment mounted on the inner surface of a curved housing HO for treatment of a patient lying on a further, planar array of LED's, for treatment of a section of the patient from all sides. The housing HO is slidable along the length of the patient so as to treat a selected area of the patient. Sections of the planar array of LED's are switchable so as to illuminate only the selected section.

**[0049]** Figures 20a and 20b show a sixteenth embodiment comprising a front-facial LED array  $L_F$  for directing light onto the face of the patient from the front, a scalp LED array  $L_S$  and left and right side-facial LED arrays  $L_L$ ,  $L_R$  moveably connected, for example by hinges, to the front-facial array  $L_F$ , for directing light onto the scalp, left side of the face and right side of the face respectively. The front-facial array  $L_F$  is slideably attached to a stand ST for vertical adjustment to the head height of the patient, preferably when sitting.

**[0050]** Figure 21 shows a seventeenth embodiment, similar to that of Figures 20a and 20b, except that it is arranged for facial and/or scalp treatment of a patient when lying down. The stand ST is mounted on a bed, instead of being free-standing, and the arrays are rotated by  $90^\circ$  so as to correspond to the position of the patient's head when lying down.

**[0051]** Figures 22a, 22b and 22c show an eighteenth embodiment in which an LED array L is mounted on the inner surface of a sleeve SL so as to direct light onto the hand, forearm and/or elbow within the sleeve.

**[0052]** Figures 23a and 23b show respectively a square and a rectangular LED array L in a nineteenth embodiment mounted on a flexible backing member FB which can be applied to an area of the patient to be treated, such as part of the forearm as shown in Figure 23c, with the LED's facing inwardly. The LED array thereby follows the contours of the area to be treated. The flexible backing member FB may be cooled by a fan which is either discrete or connected thereto by a flexible membrane which is fixed around the flexible backing member FB and directs air from a fan onto the backing member, through which the air is vented.

**[0053]** Figure 24 shows an LED array in a twentieth embodiment arranged on the surface of a cylindrical intraluminal

probe, while Figure 25 shows an LED array in a twenty-first embodiment arranged on the surface of a spherical head of an intraluminal probes. The probes are dimensioned for vulval, cervical, endometrial, bladder, gastrointestinal, oral, nasal, aural and/or bronchial treatment.

**[0054]** In tests performed by the inventor, the efficacy of PDT using red (approximately 630 nm) emission from LED's was established in *in-vivo* comparative studies using a sub-cutaneous mammary tumour regrowth delay assay. Using radiobiological end-points, it was shown that the solid-state prototype efficacies were comparable to that of expensive conventional lasers for PDT (i.e. no significant difference,  $p=0.21$ ). These results were confirmed in further clinical studies in the treatment of Bowen's disease and basal cell carcinomas where comparative complete response rates were achieved as compared to laser PDT.

**[0055]** Figure 26 shows a more specific example of the nineteenth embodiment, consisting of rows of blue LED's  $L_B$  interspersed with rows of red LED's  $L_R$  so as to form a discrete LED array composed of different types of LED as described above. The blue LED's  $L_B$  are switchable on and off together, independently of the red LED's  $L_R$  which are also switchable on and off together. In this way, red or blue illumination may be chosen according to the type of treatment and penetration depth required.

**[0056]** The blue LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 370 to 450 nm, and preferably 400 to 430 nm. This range is particularly suitable for the treatment of pre-cancerous conditions, in particular actinic keratoses.

**[0057]** The red LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 620 to 700 nm. This range is particularly suitable for the treatment of non-melanoma, such as basal cell or squamous cell carcinoma, or mycosis fungoides.

## Claims

1. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on a flexible backing, the array including light-emitting diodes of a first type having a first emission spectrum and light-emitting diodes of a second type having a second emission spectrum different from the first emission spectrum.
2. A light source according to claim 1, wherein said light-emitting diodes of the first type are independently switchable from said light-emitting diodes of the second type.
3. A light source according to claim 1 or 2, wherein said first emission spectrum is substantially in the range 370 to 450 nm.
4. A light source according to claim 3, wherein said first emission spectrum is substantially in the range 400 to 430 nm.
5. A light source according to any preceding claim, wherein said second emission spectrum is substantially in the range 620 to 700 nm.
6. Use of a light source according to any preceding claim, in the treatment of a pre-cancerous condition.
7. Use according to claim 6, wherein said pre-cancerous condition is an actinic keratosis.
8. Use of a light source according to any one of claims 1 to 5, for the treatment of a non-melanoma.
9. Use according to claim 8, wherein said non-melanoma is a basal cell or squamous cell carcinoma.
10. A light source for therapy and/or diagnosis, comprising a non-planar array of discrete light-emitting diodes mounted on a head portion for attachment to the head of a patient such that light is emitted onto the face of the patient.
11. A light source for therapy and/or diagnosis, comprising a first rigid array of light-emitting diodes, a second rigid array of light emitting diodes movably connected to an edge of the first array and a third rigid array of light-emitting diodes movably connected to another edge of the first array.
12. A light source as claimed in claim 11, further including a fourth array of light-emitting diodes movably to a further edge of the first array.
13. A light source as claimed in claim 11 or 12, arranged for treatment of the face and/or scalp.

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14. A light source for therapy and/or diagnosis, comprising a support for supporting the patient and an array of light-emitting diodes mounted on the curved inner surface of a rigid cover arranged to cover at least part of the length of a patient when supported by the support.
- 5 15. A light source as claimed in claim 14, wherein said support includes a further array of light-emitting diodes.
16. A light source as claimed in claim 15, wherein said further array comprises a plurality of sections which are independently switchable.
- 10 17. A light source as claimed in any one of claims 14 to 16, wherein said further array is planar.
18. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.
- 15 19. A light source as claimed in claim 18, wherein the aperture and housing are dimensioned to allow one or both elbows of the patient to be inserted into the housing.
- 20 20. A light source for therapy or diagnosis of a patient, comprising a plurality of independently switchable co-planar arrays of light-emitting diodes.
21. A light source for therapy or diagnosis of a patient, comprising a housing in the form of a trapezoid prism open at the base and having an upper inner surface carrying an array of light-emitting diodes.
- 25 22. A light source as claimed in claim 21, wherein at least one of the inner side faces is reflective.
23. A light source as claimed in claim 21, wherein at least one of the inner side faces carries a further array of light-emitting diodes.
- 30 24. A light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on a surface thereof an array of discrete light-emitting diodes.
25. A light source as claimed in claim 24, wherein said surface is substantially cylindrical.
- 35 26. A light source as claimed in claim 24, wherein said surface is substantially spherical.
27. A therapeutic light source, comprising an array of light-emitting diodes arranged so that light from the light-emitting diodes is incident directly on the treatment field with an intensity of at least approximately 10 mW/cm<sup>2</sup>, and means for cooling the diodes by forced air convection.
- 40 28. A therapeutic light source, comprising an array of discrete light-emitting diodes arranged to give an output intensity of at least approximately 10 mW/cm<sup>2</sup>, and means for cooling the diodes by forced air convection.
- 45 29. A light source as claimed in claim 27 or 28, arranged so that light from the light-emitting diodes has a spatial intensity fluctuation of approximately 10% or less in the treatment field.
30. A light source as claimed in any preceding claim, wherein the diodes are thermally coupled to one or more heat-sinks.
- 50 31. A light source as claimed in claim 27, wherein the diodes are mounted at the distal end of a passage for carrying the air from the proximal to the distal end.
32. A light source as claimed in claim 31, including a fan mounted at the proximal end of the passage.
- 55 33. A light source as claimed in claim 31 or claim 32, wherein the distal end is dimensioned so as to be locatable proximate a cervix such that light from the diode array is incident on the cervix.
34. A light source as claimed in claim 33, wherein the distal end is concave so as to fit over the cervix.

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35. A therapeutic light source, comprising an array of discrete light emitting diodes coupled to a tapered light guide arranged to concentrate light emitted by the light-emitting diodes.
- 5 36. A light source according to claim 35, including a parallel-sided light guide coupled to the tapered light guide so that the light emitted by the light-emitting diodes is concentrated into the parallel-sided light guide.
37. A therapeutic light source, comprising an integrated array of light emitting diodes coupled directly to a parallel-sided light guide.
- 10 38. A light source as claimed in claim 37, wherein the diodes are thermally coupled to thermoelectric cooling means.
39. A light source as claimed in claim 35 or 37, wherein the parallel-sided light guide comprises one or more optical fibres and/or liquid light guides.
- 15 40. A therapeutic light source comprising an array of light emitting diodes having emission wavelengths substantially within the range 550 to 660 nm.
41. A light source as claimed in claim 40, wherein the emission wavelengths are substantially within the range 590 to 640 nm.
- 20 42. A light source as claimed in claim 41, wherein the diodes are of aluminium indium gallium phosphide/gallium phosphide die material.
43. A light source as claimed in claim 42, wherein the emission wavelengths are substantially within the range 560 to 644 nm.
- 25 44. A light source as claimed in claim 43, wherein the diodes are of aluminium indium gallium phosphide/gallium arsenic die material.
- 30 45. A light source as claimed in claim 42, wherein the emission wavelengths are substantially within the range 650 to 660 nm.
46. A light source as claimed in claim 45, wherein the diodes are of aluminium gallium arsenic die material.
- 35 47. A light source as claimed in claim 42, wherein the emission wavelengths are substantially within the range 550 to 570 nm.
48. A light source as claimed in claim 47, wherein the diodes are of gallium phosphide die material.
- 40 49. A therapeutic light source comprising an array of LED's with peak emission spectra of approximately 470 nm, 505 nm or 525 nm.
50. A light source as claimed in claim 49, wherein the diodes are of indium gallium nitride die material.
- 45 51. A therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm.
52. A light source as claimed in claim 51, wherein the diodes are of gallium nitride/silicon die material.
53. A light source as claimed in any preceding claim, wherein said LED's include a first set of LED's and a second set of LED's having different emission spectra from said first set.
- 50 54. A light source as claimed in any one of claims 27 to 36 and 40 to 52, or claim 53 when dependent thereon, wherein the array is mounted on a flexible circuit board.
- 55 55. A therapeutic light source, comprising an LED array including a first set of LED's and an independently switchable second set of LED's having different emission spectra from said first set.
56. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second, spatially

distinct set of LED's independently switchable from said first set.

**57.** Use of a light source as claimed in any preceding claim, for cosmetic treatment of a patient.

5 **58.** Use as claimed in claim 57, for photodynamic treatment of the patient.

**59.** Use as claimed in claim 58, for portwine stain removal, or hair restoration or removal.

**60.** Use as claimed in claim 57, for skin rejuvenation, wrinkle removal or biostimulation.

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**61.** Use of a light source as claimed in any one of claims 1 to 56, for medical treatment of a patient.

**62.** Use as claimed in claim 61, for photodynamic treatment of a patient.

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**63.** Use as claimed in claim 62, in the treatment of one or more of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barrett's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism.

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**64.** A light source for therapy or diagnosis substantially as herein described with reference to and/or as shown in Figures 1 to 4, or Figure 5, or Figure 6, or Figure 7, or Figure 8, or Figure 9, or Figures 10a and 10b, or Figures 11a to 11c, or Figure 12, or Figure 13, or Figure 14, or Figure 15, or Figures 16a and 16b, or Figures 17a and 17b, or Figures 18a and 18b, or Figures 19a and 19b, or Figures 20a and 20b, or Figure 21, or Figures 22a to 22c, or Figures 23a to 23c, or Figure 24, or Figure 25, or Figure 26 of the accompanying drawings.

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Fig. 1

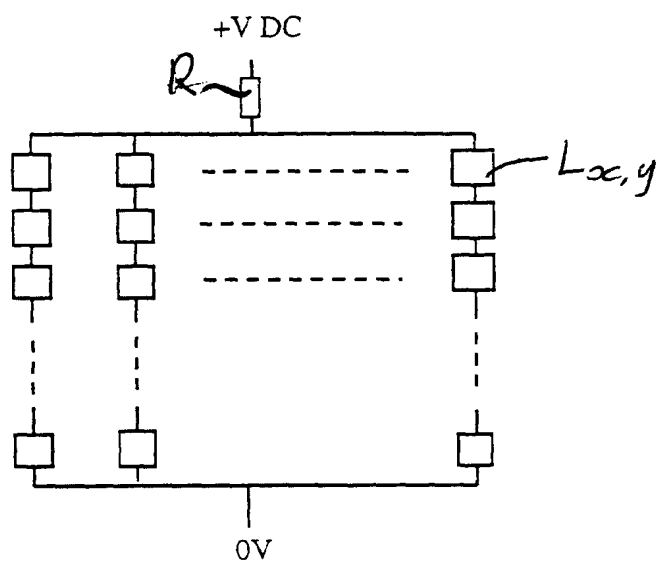


Fig. 5

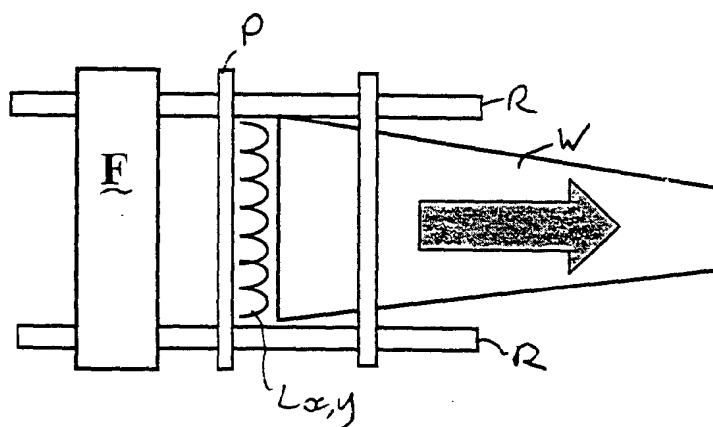


Fig. 2

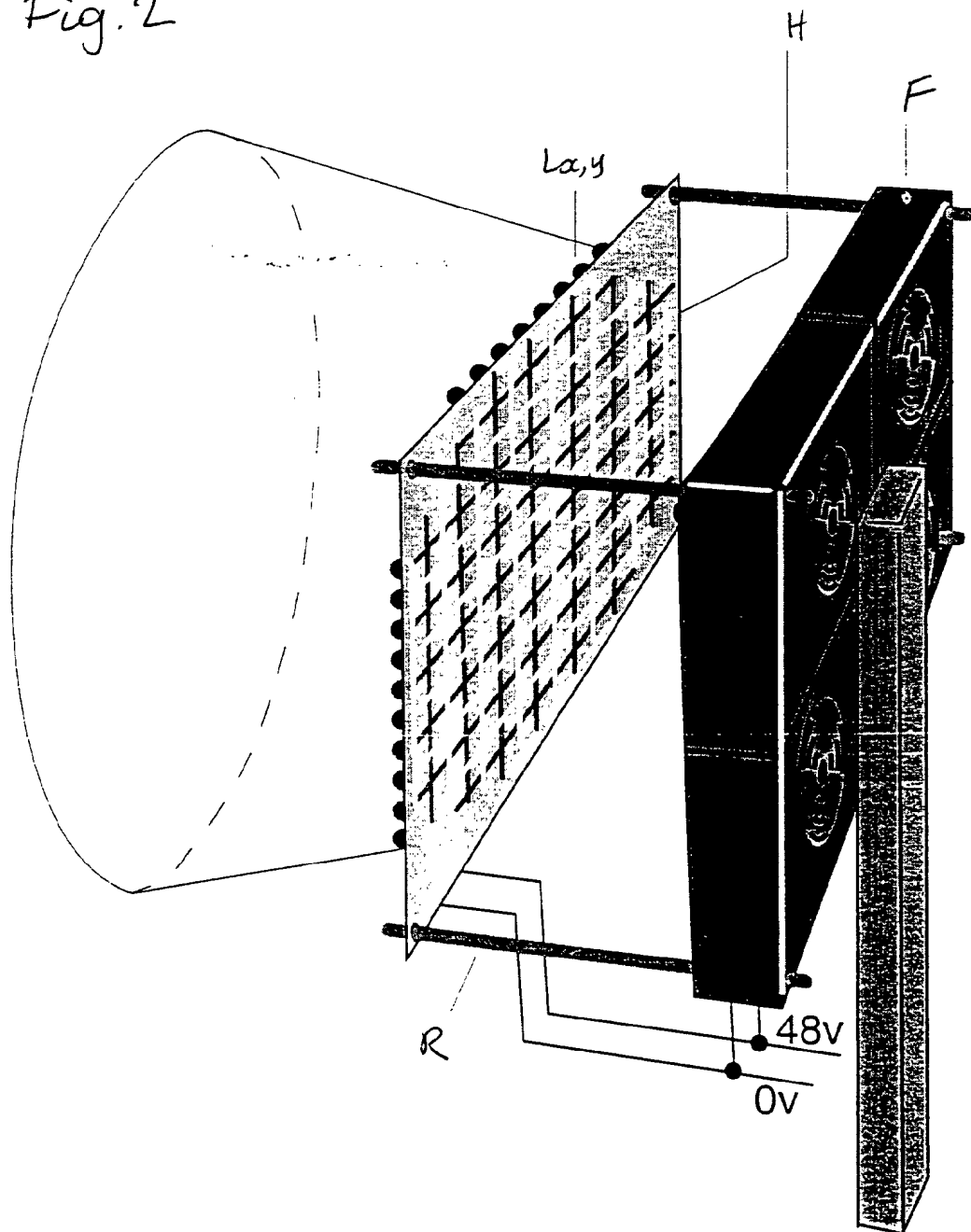


Fig. 3

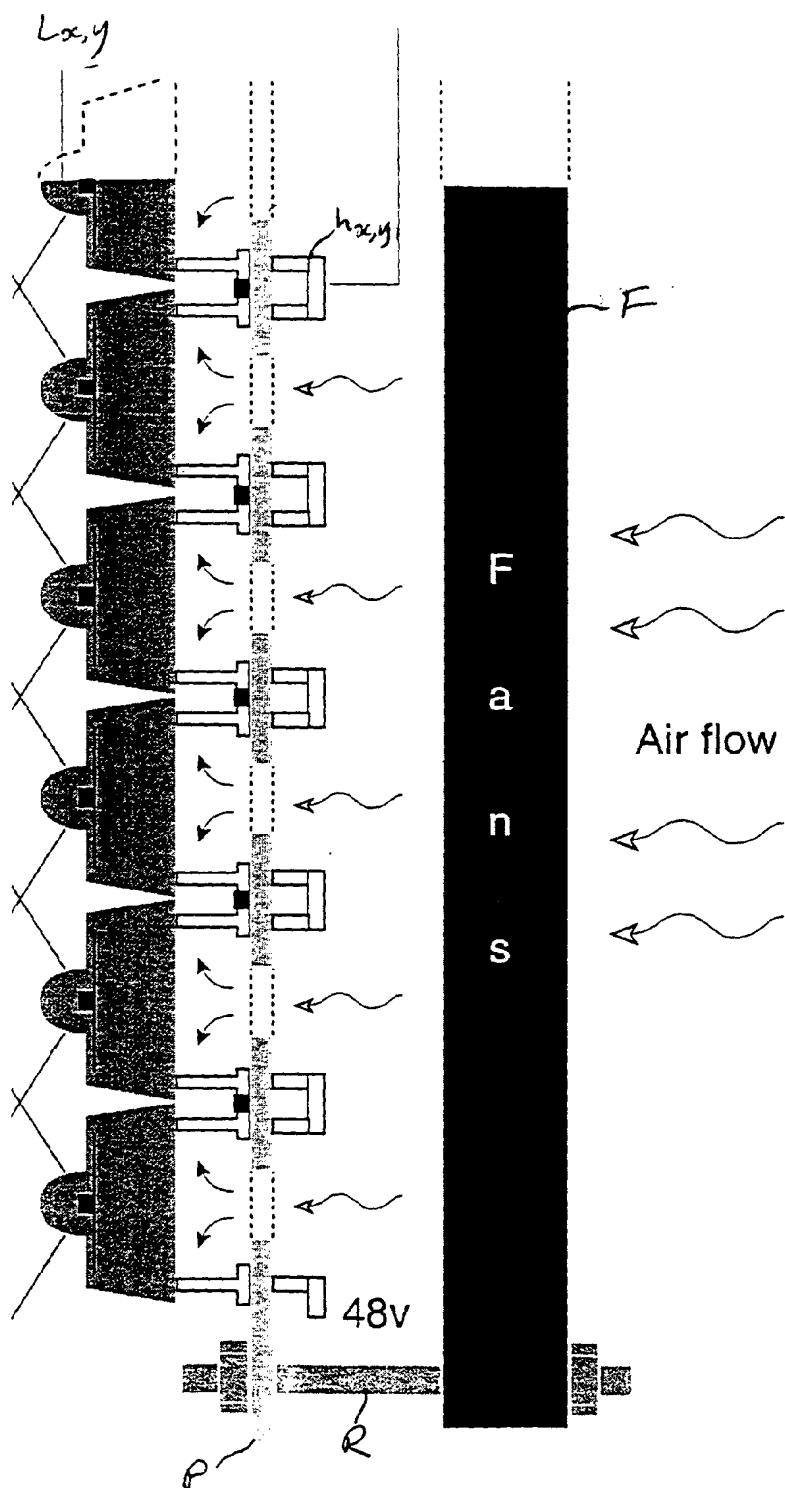


Fig. 4

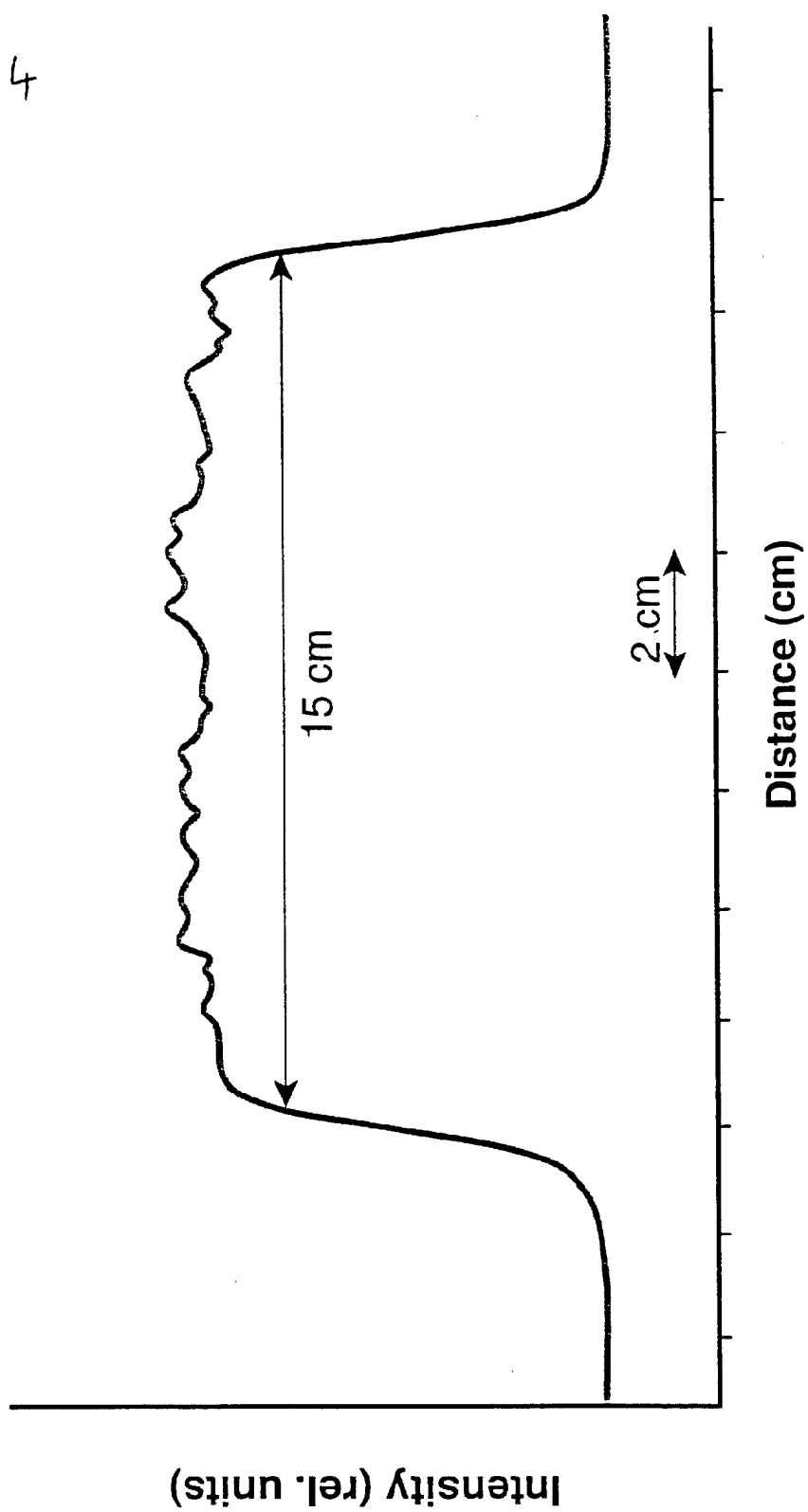


Fig. 6

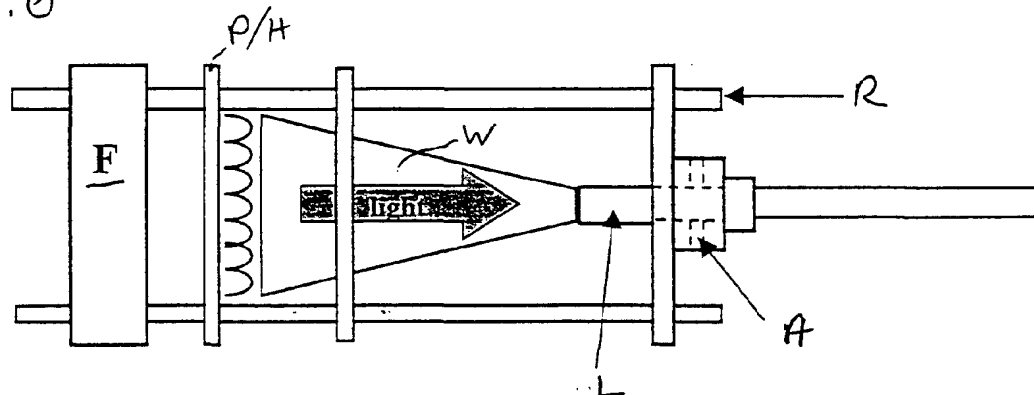


Fig. 7

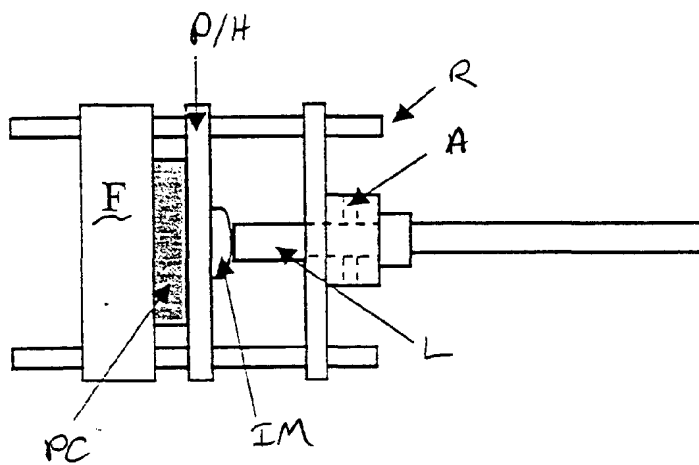
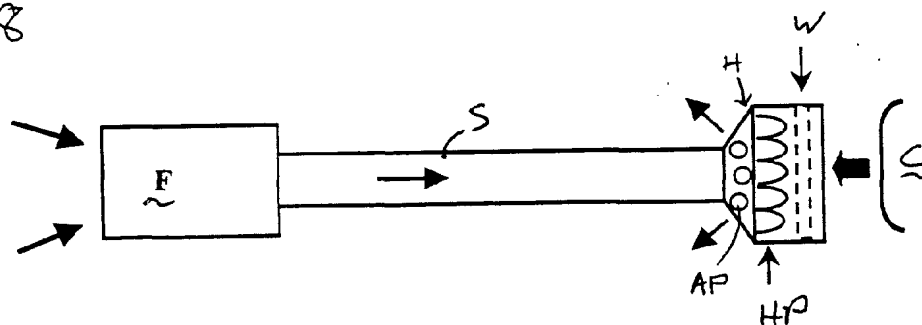


Fig. 8



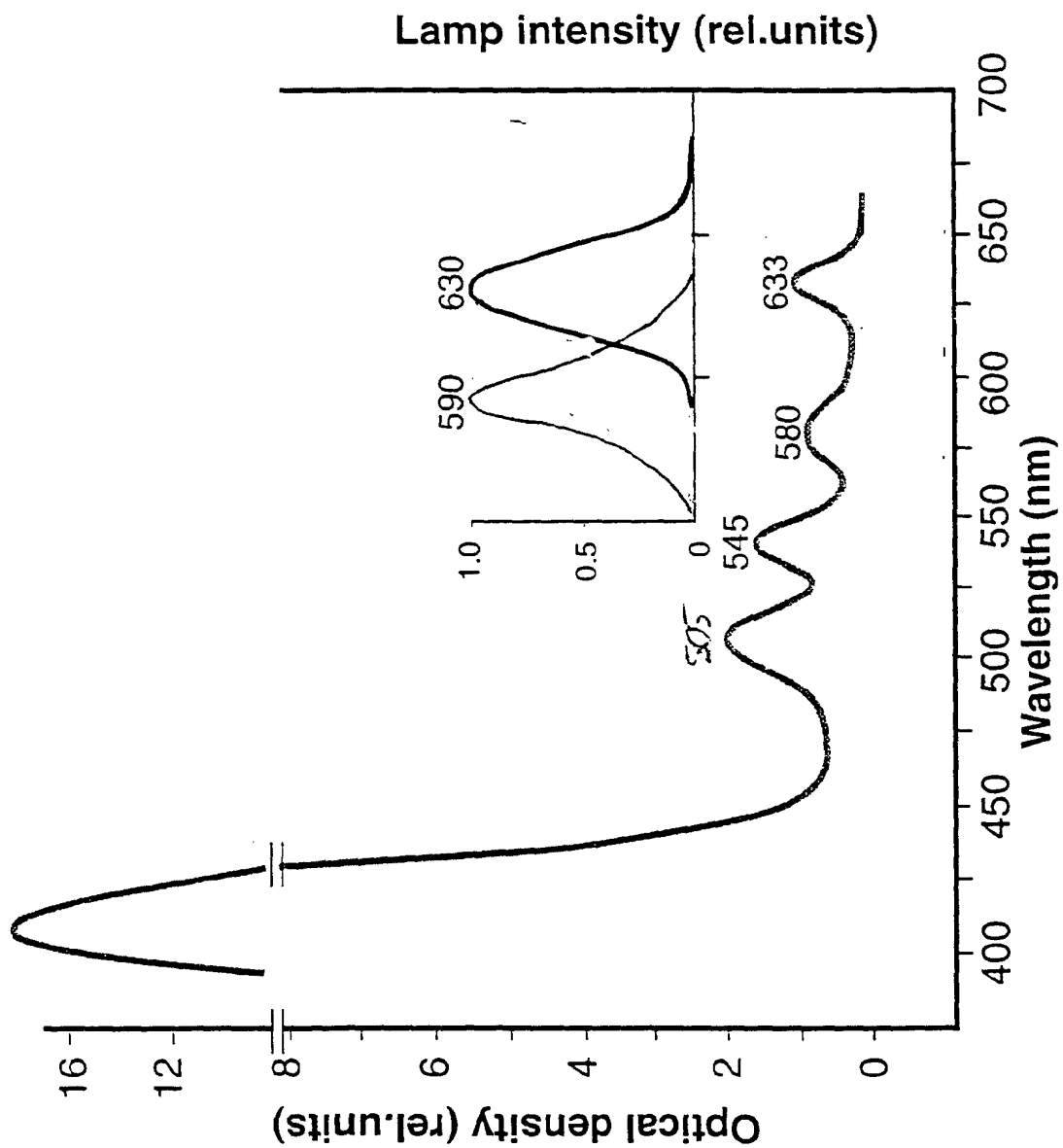


Fig. 9

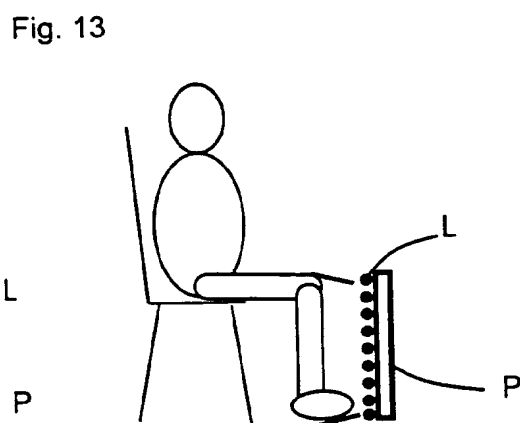
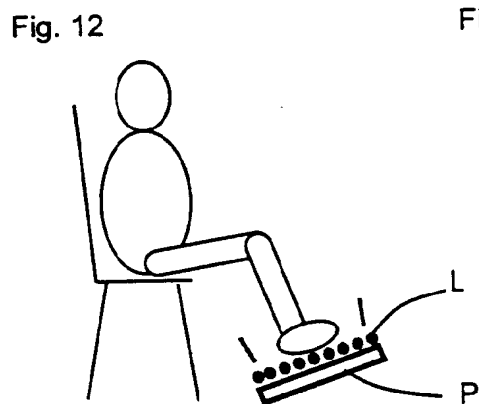
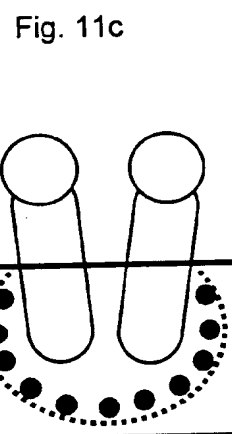
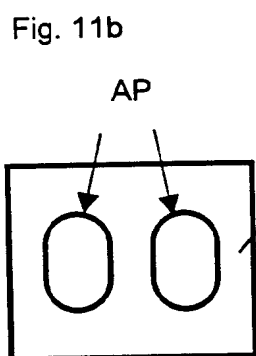
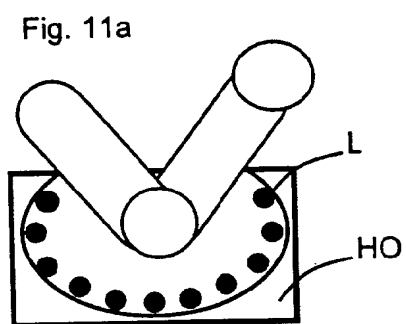
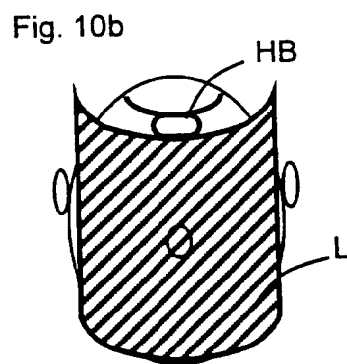
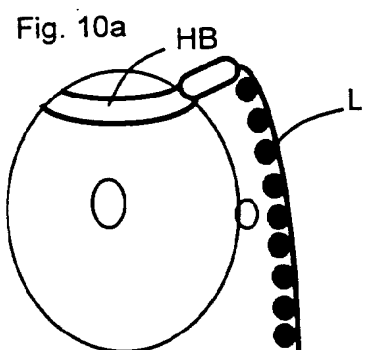


Fig. 14

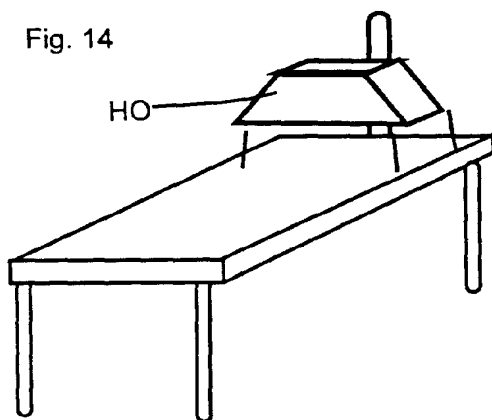


Fig. 15

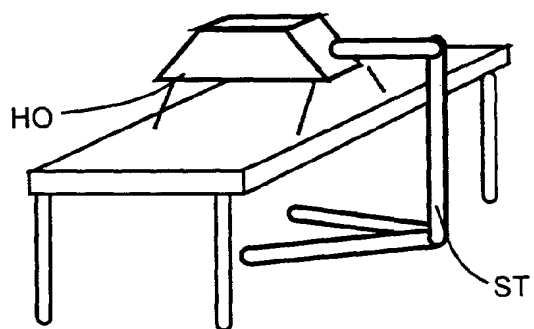


Fig. 16a

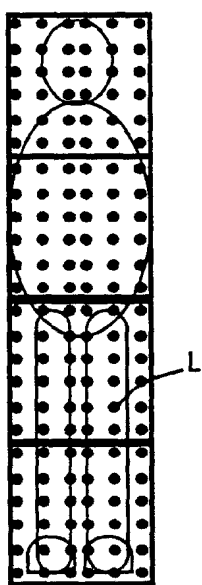


Fig. 16b

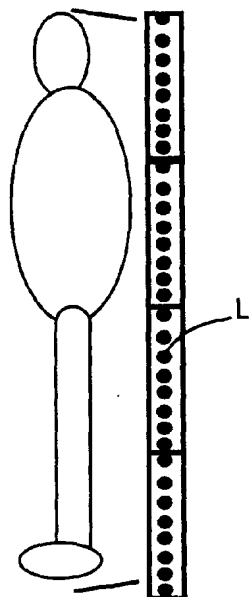


Fig. 17a

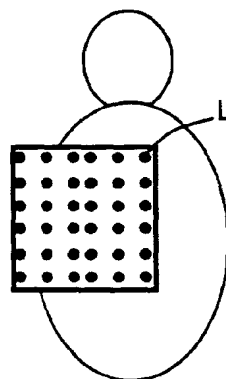


Fig. 17b

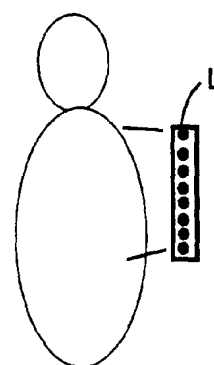


Fig. 18a

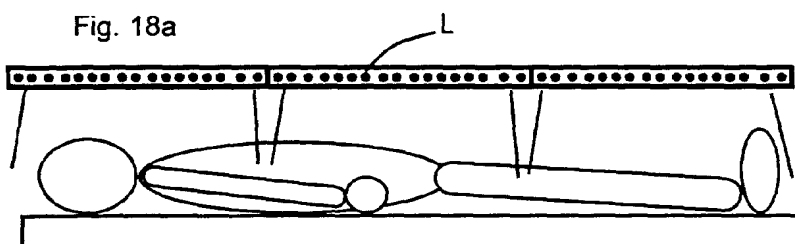
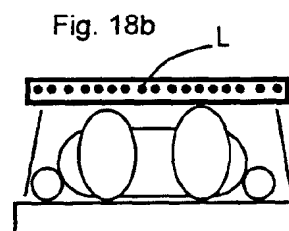
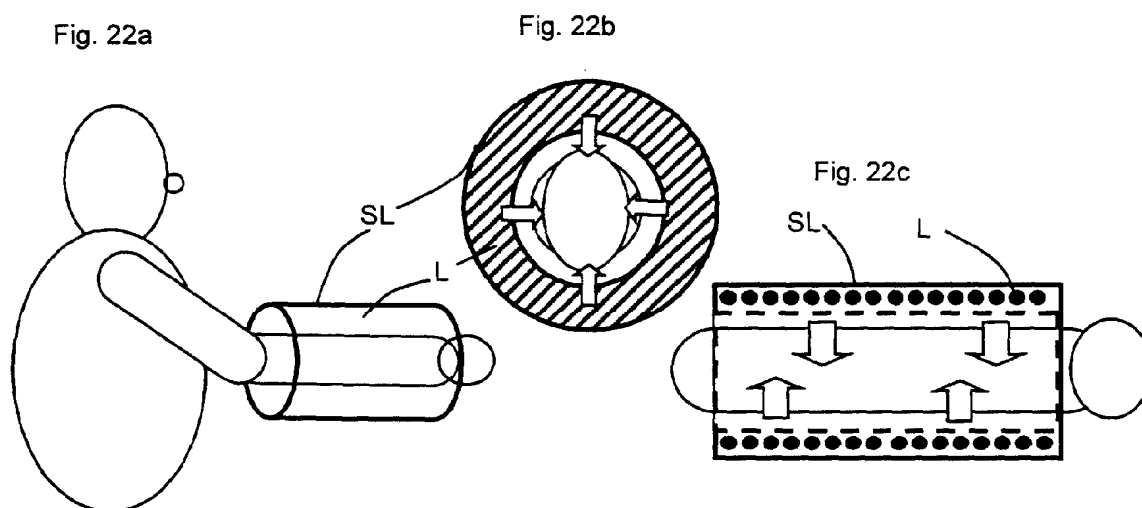
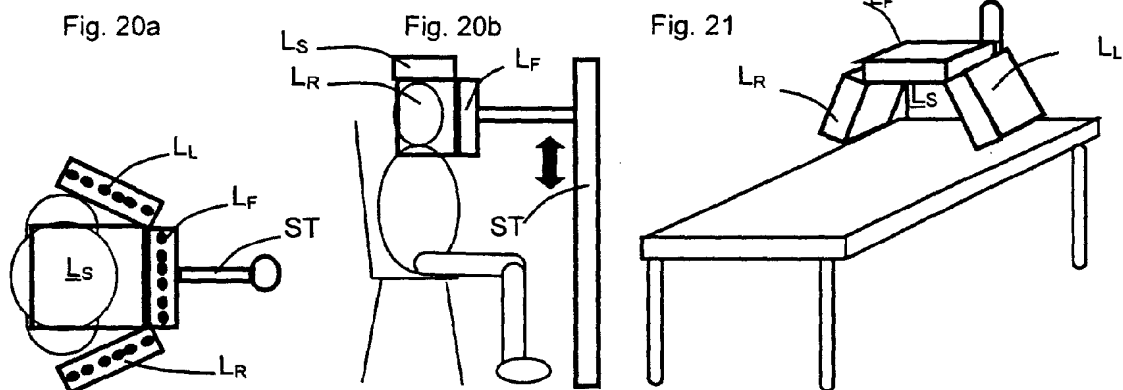
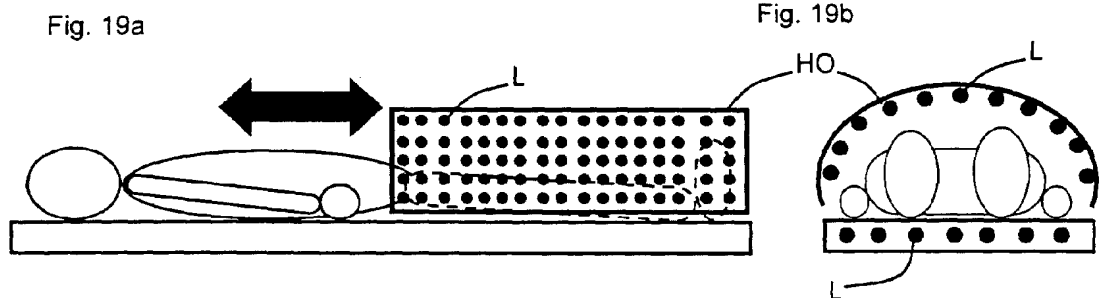
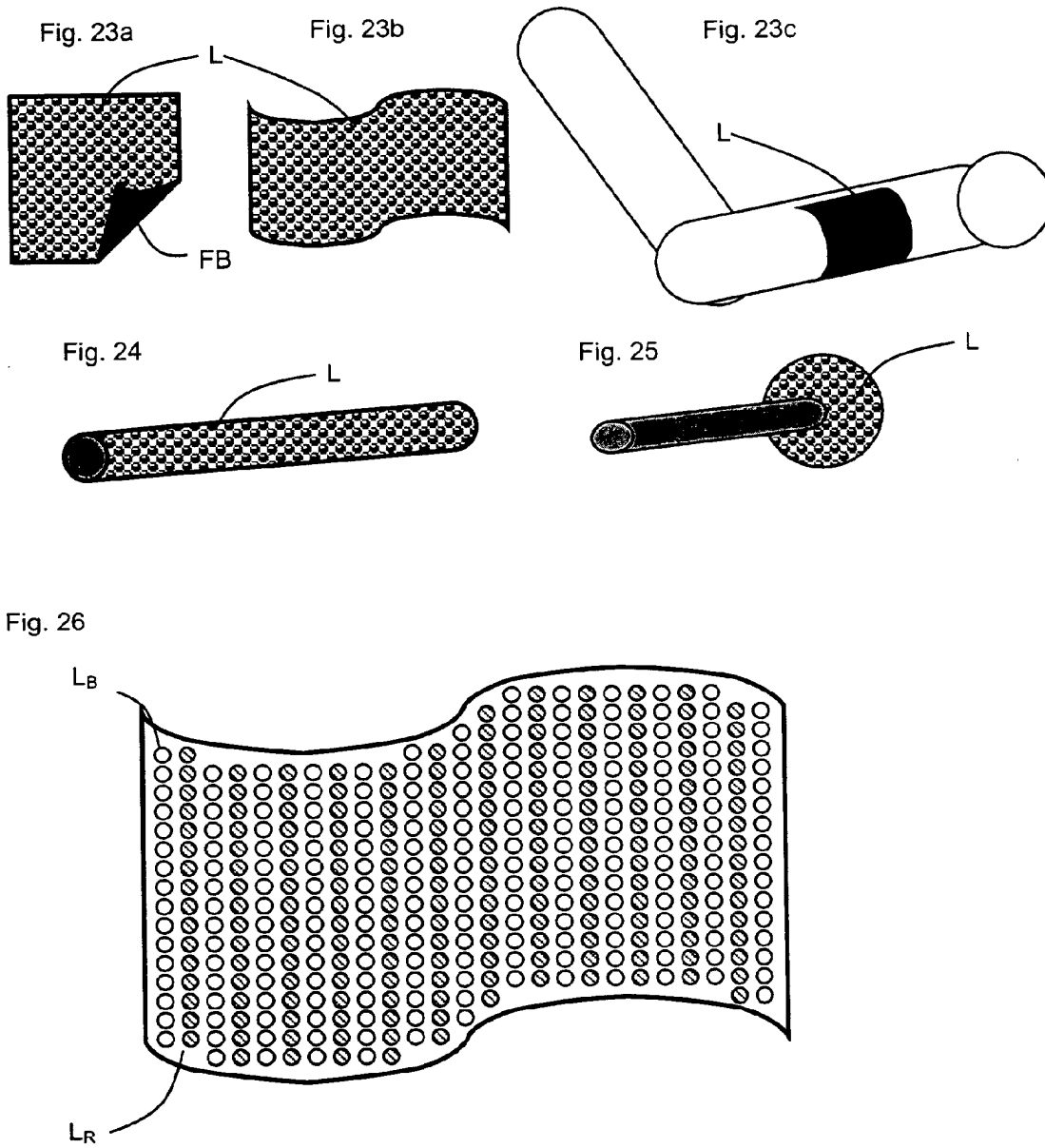


Fig. 18b











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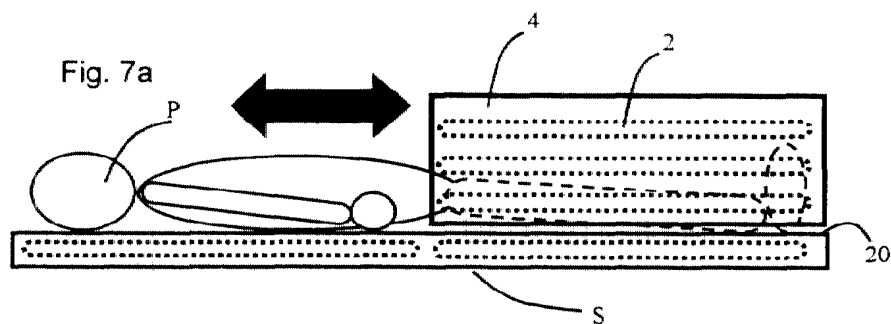
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(54) **Therapeutic light source**

(57) A light source for therapy, such as photodynamic therapy, comprises one or more low pressure or medium/high pressure discharge tubes. In one aspect, the light source comprises a non-planar array of substan-

tially straight tubes. In another aspect, the light source comprises one or more such tubes mounted in a housing having an aperture allowing part of the patient to be located within the housing.



## Description

**[0001]** The present invention relates to a non-coherent light source for use in therapy such as photodynamic therapy (PDT), particularly but not exclusively for treating large external surfaces of a patient, and/or a method of use thereof.

**[0002]** Photodynamic therapy involves the administration of a photosensitising drug to an affected area, and its subsequent irradiation with light - see for example 'The Physics of Photodynamic Therapy' by B C Wilson and M S Patterson, Physics in Medicine & Biology 31 (1986) April No. 4, London GB.

**[0003]** The document WO 97/40888 proposes the use of one or more fluorescent tubes to emit yellow, orange and/or red wavelengths in a lamp for PDT. However, the coefficient of absorption of many PDT drugs for PDT, and of human tissue, is relatively low in these wavelengths, so that the light will have a high penetration depth and is unsuitable for treating superficial conditions. Moreover, the activation efficiency of most PDT drugs is low at these wavelengths and the light intensity available from fluorescent tubes is also comparatively low, which will lead to long treatment times.

**[0004]** The document WO 99/56827 discloses a light source for PDT treatment or diagnosis of the scalp or face, comprising U-shaped fluorescent tubes which emit preferably blue light. This light source would be expensive to manufacture as the U-shaped tubes would have to be manufactured specifically for this application.

**[0005]** According to one aspect of the present invention, there is provided a therapeutic light source comprising a non-planar array of substantially straight fluorescent tubes arranged to emit light substantially within the visible spectrum.

**[0006]** In one embodiment, the array may be mounted on a surface curved perpendicular to the length of the tubes.

**[0007]** In another embodiment, the array may be mounted on at least two planar surfaces set at an angle to one another.

**[0008]** According to another aspect of the present invention, there is provided a therapeutic light source comprising one or more fluorescent grid lamps each comprising a tube having a plurality of folds in the same plane.

**[0009]** According to another aspect of the present invention, there is provided a therapeutic light source comprising a discharge tube and a concave reflector arranged to concentrate light on an area to be treated. In one embodiment, the light source is mounted in a housing having an aperture allowing part of the patient to be located within the housing.

**[0010]** According to another aspect of the present invention, there is provided a light source for PDT including one or more medium/high pressure discharge lamps arranged to emit narrow bandwidth light directly, such that it impinges on a patient with an intensity of at least 3 mW/cm<sup>2</sup>, preferably between 10 and 100 mW/cm<sup>2</sup>, and no greater than approximately 200 mW/cm<sup>2</sup>. Such medium/high pressure discharge lamps can produce a greater intensity than low-pressure fluorescent lamps, while still providing the advantage of narrow bandwidth light over a large area without the need for intervening optics.

**[0011]** Preferably, the bandwidth of the medium/high pressure discharge lamp(s) is 160 nm or less.

**[0012]** Preferably, the arc length of the medium/high pressure discharge lamp(s) is at least 15 mm.

**[0013]** The or each medium/high pressure discharge lamp may be straight or have a folded or serpentine shape.

**[0014]** In either aspect, preferably the one or more lamps are arranged in a housing having a window or aperture through which light impinges on the patient, and preferably a reflector arranged to reflect light specularly or diffusely from the lamps through the window or aperture. The reflector is preferably arranged to provide a uniform output.

**[0015]** The present invention includes a method of use of the light source for PDT, in which a topical photosensitizer such as 5-aminolaevulinic acid (5-ALA) is applied to the affected area of the patient and light from the light source is subsequently applied. Preferably, the method is used to treat superficial oncological or non-oncological conditions. Preferably, the method is used to treat one or more of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, psoriasis, eczema, nevus sebaceous, viral infections such as herpes simplex, molluscum contagiosum, warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata or hirsutism. Preferably, the total treatment time is no greater than one hour per session.

**[0016]** The present invention further includes a method of cosmetic or partially cosmetic treatment with a photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

**[0017]** Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a schematic circuit diagram of a fluorescent tube array in an embodiment of the present invention;

Figure 2 is a front view of the tube array in a housing;

Figure 3 is a cross-section along the plane A-A perpendicular to Figure 2;

Figure 4 is a profile of the beam intensity of the tube array across the treatment field;

Figure 5 shows the absorption spectrum of PpIX, the emission spectrum of a prior art lamp and the emission spectrum of the fluorescent tubes of the tube array;

Figures 6a and 6b are respectively longitudinal and transverse schematic diagrams of a lamp using medium/high pressure discharge tubes for full-length treatment of one side of a patient;

Figures 7a and 7b are respectively longitudinal and transverse schematic diagrams of a lamp using straight fluorescent discharge tubes for treatment of a section of a patient;

Figures 8a and 8b show a variant of the arrangement of Figures 7a and 7b, for full-length treatment of a patient;

Figures 9a and 9b are schematic diagrams of a lamp, respectively in use and with a door open for access, using fluorescent tubes for treatment of the lower half of a patient's body;

Figures 10a and 10b are respectively frontal and side schematic views of a lamp using fluorescent tubes arranged on the reflective inner surface of a walk-in booth;

Figures 11a and 11b are respectively frontal and side schematic views of a lamp using medium/high pressure discharge tubes, for treatment of one side of the patient in a standing position;

Figures 12a and 12b are respectively frontal and side schematic views of a grid lamp positioned to illuminate part of the patient to be treated;

Figures 13a and 13b are respectively frontal and side schematic views of a lamp comprising four substantially coplanar grid lamps arranged in a row, to illuminate the whole length of a patient;

Figure 14 is a perspective view of a lamp using medium/high pressure discharge tubes for facial treatment, mounted on a bed;

Figure 15 is a perspective view of a free-standing version of the arrangement of Figure 14;

Figures 16 to 18 are side views, partially in cross-section, of lamps comprising an array of parallel fluorescent discharge tubes, for treatment of the foot, lower leg and full leg respectively;

Figures 19a to 19c are respectively a cross-section in the plane of an arm, a top view and a vertical cross-section perpendicular to the plane of the arm of a patient, of a lamp using a medium/high pressure tube for treatment of the elbows of a patient;

Figures 20a and 20b are top and side views, respectively, of a lamp comprising medium/high pressure discharge tubes, for treatment of the face and/or scalp of a patient in a sitting position; and

Figure 21 is a perspective view of a lamp similar to that of Figures 20a and 20b, but mounted on a bed for treatment of a patient lying down.

**[0018]** In an embodiment shown in Figures 1 to 3, six similar fluorescent tubes 2 are mounted parallel in an array in a generally cuboid hollow housing 4 made of polished stainless steel. The tubes 2 are electrically connected to electronic ballasts 6 for initiating and maintaining current flow through the tubes 2. The ballasts 6 are powered by an a.c. mains power supply 8. A fan 10, also driven by the mains power supply 8, is arranged to draw air through vents (not shown) in the housing 4 so as to cool the tubes 2.

**[0019]** Each of the tubes is securely engaged in a resilient mounting bracket 12 at each end attached to a back wall 14 of the housing 4. On the internal surface of the back wall 14 is a white diffuse reflector 16 arranged to reflect diffusely towards the front of the light emitted by the tubes 2. The diffuse reflector 16 may be made of a white self-adhesive plastic sheet (e.g. Fablon™) or a removable sheet of paper or other material which can easily be replaced if it becomes dirty. Instead of a diffuse reflector, a non-planar specular reflector may be used to provide a uniform beam, such as a dimpled metal reflector as is often used in high power security lamps.

**[0020]** The housing 4 has an aperture 18 in its front surface substantially conforming in size and shape to the extent of the light-emitting portions of the array of tubes 2. The aperture 18 is covered by a transparent or translucent lid 20, for example of plastic such as clear polycarbonate, e.g. Makrolon™. The lid 20 is removable to allow access to and replacement of the tubes 2. The lid 20, when in place, serves to protect the internal components and the patient from each other. Preferably, the housing 4 is placed horizontally with the aperture 18 facing upwards and the patient lies on or rests the affected area on the lid 20, which is strong enough to support the patient or affected area.

**[0021]** The lid 20 may filter the light emitted by the tubes 2 before it impinges on the patient. For example, the lid 20 may comprise or include a layer of material which filters out part of the emission spectrum of the tubes 2. The material may filter out UV radiation and/or parts of the visible spectrum which do not excite the relevant photosensitising drug. The layer of material may be removably attached to a support forming part of the lid 20, such as guide rails, to allow the filtering layer to be exchanged for another filtering layer, or removed completely.

**[0022]** In one example, the length *a* of the housing 4 is 600 mm, the width *b* is 300 mm, and the depth *c* is 70 mm.

**[0023]** The diffuse reflector 16 and the spacing of the tubes 2 gives a beam profile as shown in Figure 4. In this example, the tubes are 38 mm in diameter and there is a 15 mm gap between adjacent tubes. Across the width (in the direction of the width *b* of the housing 4) of the treatment field, which extends over about 30 cm, the beam intensity varies by no more than approximately 6%. This degree of uniformity minimises the risk of some areas of the patient's skin receiving less than the threshold light dose, which is important to prevent recurrence of the disease being treated.

**[0024]** The tubes 2 have a fluorescent coating selected so as to emit light with a narrow spectrum coincident with an absorption peak of a photosensitive drug, and substantially confined within a range of 350 to 500 nm, most preferably

400 to 450 nm. Figure 5 shows the output spectrum of a suitable fluorescent tube, reference TL/03, such as part no. TLK 40/03 available from Philips, which is commercially available and used in diazo printing. The spectrum shows the main peak at 420 nm with additional very narrow, low energy peaks at 435 nm and 546 nm.

[0025] Superimposed on the graph, but in relative units of optical density shown on the left hand side of the graph, is the absorption spectrum of PpIX. It can readily be seen that the absorption peak at 410 nm is much greater and broader than the absorption peak at 633 nm, or the other absorption peaks at 545 nm and 580 nm with which the output of the lamp described in WO97/40888 may coincide. Hence, for the same area of skin to which 5-ALA, a precursor of PpIX, is topically applied, the light from the lamp of the embodiment will have a substantially shorter penetration depth, and an activation efficiency approximately 20 times greater. In the treatment of superficial diseases of the skin by PDT, this will result in substantially no damage to underlying layers of skin and substantially shorter treatment times as a result of more efficient absorption by the affected tissue.

[0026] A method of treatment for superficial cases of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, psoriasis, eczema, nevus sebaceous, viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata or hirsutism will now be described. A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected area of the skin of the patient, or administered intravenously or orally. For large areas, the patient may be immersed in a bath of solution. The affected area may then be covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is then uncovered and exposed to light from the lamp as described in any of the embodiments for a period of 15 to 30 minutes. The treatment may then be repeated as necessary, for a total of 1 to 3 treatments or more, depending on the severity and type of the condition. This method is particularly suitable for the treatment of patients with very large lesions or multiple lesions extending over a large area.

[0027] The lamp may also be used for fluorescence detection (photodiagnosis).

[0028] The lamp may also be used for cosmetic or partially cosmetic treatment with a photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

[0029] The lamp may be scaled up or down in size so that the effective treatment area (as defined for example as the extent of substantially uniform illumination as shown in Figure 4) extends over the whole body of a patient or just the area to be treated. The whole-body size is particularly suitable for the treatment of psoriasis, mycosis fungoides and pre-malignant skin diseases.

[0030] The lamp may include an electro-optical detector arranged to monitor the light dose delivered and to switch off the light emission when a target dose is reached. Alternatively, or additionally, the detector is arranged to monitor the instantaneous light intensity and to vary the electrical power supplied to the tubes so as to maintain the intensity within predetermined limits, and/or to switch off the light emission if a maximum limit is exceeded.

[0031] In an alternative embodiment, TL/52 fluorescent tubes, having a peak emission at approximately 450 nm, are used in place of the TL/03 tubes. However, the TL/52 tubes are less desirable because of the lower absorption of PpIX around this wavelength.

[0032] In an alternative embodiment, low pressure 'grid lamps' comprising low pressure mercury or xenon arc lamps may be used. These 'grid lamps' are formed of narrow bore silica or glass tubes, with an outside diameter of less than approximately 13 mm and preferably approximately 9 mm, folded in a serpentine shape to give an overall arc length of between a few centimetres and 10 metres. Preferably, the tube is made from quartz, which transmits UV light. A phosphor is therefore coated onto the outside of the tube, or onto the bore of a second, outer concentric tube.

[0033] In any of the embodiments which use fluorescent tubes, the full circumference of each tube, or at least 70% thereof, is coated with phosphor. Where only part of the circumference is coated with phosphor, the remaining part may be coated with reflective material to reflect the discharge radiation onto the phosphor-coated part of the tube. Such tubes are arranged to concentrate light towards the patient.

[0034] The phosphor gives an emission wavelength substantially coincident with photosensitiser absorption spectra, as shown in Table 1 below.

TABLE 1 -

Photosensitiser Absorption Spectra			
Photosensitiser	Red absorption band	Red peak	Blue/ green peak
Naphthalocyanines	780 - 810		
Chalcogenopyrillium dyes	780 - 820		

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TABLE 1 - (continued)

Photosensitiser Absorption Spectra			
Photosensitiser	Red absorption band	Red peak	Blue/ green peak
Phthalocyanines (e.g. ZnII Pc)	670 - 720	690	
Tin ethyl etiopurpurin (SnET <sub>2</sub> )	660 - 710	660-665	447
Chlorins (e.g. N-Aspartyl chlorin e6 or NPe6)	660 - 700	664	
Benzoporphyrin derivative (BPD)		685/690	456
Lutetium texaphrin (Lu-TeX)		735	
Al(S <sub>1</sub> /S <sub>2</sub> /S <sub>3</sub> /S <sub>4</sub> )Pc	660 - 710	670/685	410,480
Photofrin		625/630	405
Protoporphyrin IX (PpIX) (from 5/δAminolaevulinic Acid (5ALA))		635	410,505,540 , 580
Tetra m-hydroxyphenyl Chlorin (mTHPC)		650	440, 525

[0035] Two or more phosphors may be mixed together in the coating to give the required emission spectra. Different phosphor coatings available from BHK, Inc., Claremont USA have the following properties shown below in Table 2:

TABLE 2 -

BHK Phosphor Peak Emissions and Bandwidths	
Peak Emission Wavelength (nm)	Bandwidth (nm)
406	41
418	29
430	114
460	105
494	170

Alternative phosphor coatings available from Jelight Company, Inc., Irvine, CA, USA have the properties shown below in Table 3:

TABLE 3 -

Jelight Phosphor Peak Emissions and Bandwidths	
Peak Emission Wavelength (nm)	Bandwidth (nm)
400	37
413	34
420	34
446	112
446, 525, 580	discrete peaks
447	32
450	49
455	62
460	105
473	136

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TABLE 3 - (continued)

Jelight Phosphor Peak Emissions and Bandwidths	
Peak Emission Wavelength (nm)	Bandwidth (nm)
479	75
482	138
495	223

[0036] In yet another alternative embodiment, medium/high pressure discharge tubes are used in place of the low pressure fluorescent tubes 2, with the driving circuitry replaced accordingly. As medium/high pressure discharge tubes generally give a much higher intensity output than fluorescent tubes, the former are more widely spaced apart and have individual reflectors arranged to provide a uniform illumination. The medium/high pressure tubes have a gas fill selected to activate the photosensitiser in use, examples of which are shown above in Table 1. Sample gas and vapour fills are shown below in Table 4:

TABLE 4 -

Gas/Vapour Fills		
Type	Fill	Emission Wavelengths* (nm)
Medium Pressure mercury plus additive:	gallium	400-430
	thallium	530-550
	cadmium	440, 550, 580
	gallium + thallium	400-420, 440, 450, 540
	indium	450-460
High Pressure	gallium + lead	400-430
	sodium vapour	560-640
	sodium vapour, plus xenon or mercury	600-760
Medium Pressure Rare Gas	neon	585-670
	argon	416-488, 697
	krypton	427-587
Medium Pressure Vapour	cadmium	480, 508
	mercury	405, 436, 546, 577
	caesium	455, 852
	zinc	636
	thallium	535
	potassium	766

\* Discrete peaks shown as single peak wavelengths, emission bands shown as ranges.

[0037] Another possible fill is mercury-argon or mercury-xenon at medium or high pressure, which gives superposition of the two emission spectra together with a pressure-broadened continuum across the visible spectrum.

[0038] In an alternative embodiment, an array of high-pressure metal halide lamps may be used where the arc burns in a dense vapour of mercury and rare earth halides, giving a peak emission in the range 400 to 650 nm.

[0039] Possible alternative arrangements of the tubes in the above embodiments will now be described. In each of these arrangements, straight tubes or grid lamp tubes are used, as such shapes are commercially available at low cost. Where fluorescent tubes, grid lamp tubes or medium/high pressure discharge tubes are described, these may be any of the tubes of such type described above. In these arrangements, fluorescent tubes may be replaced by medium/high pressure discharge tubes by increasing the spacing between tubes and providing an individually shaped



reflector for each tube, except where providing such an individual reflector is impractical due to shape and size constraints. Likewise, medium/high pressure discharge tubes may be replaced by fluorescent tubes, except where this would lead to an intensity too low for practical phototherapeutic or diagnostic applications.

**[0040]** Figures 6a and 6b show a lamp using medium/high pressure discharge tubes 2', for full-length treatment of one side of a patient P. The lamp comprises three such tubes arranged parallel to each other and perpendicular to the length of the patient in a housing 4. Each tube has a curved reflector 16 arranged behind it so as to generate an approximately uniform illumination of the patient P lying on a surface S.

**[0041]** Figures 7a and 7b show a lamp using straight fluorescent discharge tubes 2, for treatment of a section of the patient P. The tubes are arranged parallel to each other and to the length of the patient P, on the inner reflective surface 16 of a curved housing 4 which can be slid relative to the patient P along the length of the patient so as to illuminate the desired section of the patient P. The surface S on which the patient rests may be the lid(s) 20 of flat lamp(s) using fluorescent tubes 2 as described above. Figures 8a and 8b show a variant in which the tubes 2 and the housing 4 extend substantially over the whole length of the patient P for full-length treatment; in this case, the housing 4 does not need to be slidable.

**[0042]** Figures 9a and 9b show a lamp using fluorescent tubes 2, for treatment of the lower half of a patient's body. The tubes are arranged on the inner reflective surface of an housing 4 within which the patient P stands. The housing 4 is a slightly tapered cylinder with a diameter which increases with height so as to keep the distance between the patient's skin and the tubes 2' approximately constant. The housing 4 may have a door for access, as shown in Figure 9b in an open position.

**[0043]** Figures 10a and 10b show a lamp using fluorescent tubes 2, arranged on the reflective inner surface of a housing 4 in the form of a walk-in booth, which may be oval, circular, rectangular, hexagonal, or other polygonal in cross-section, of constant diameter with height. The booth includes a door, the inner surface of which carries some of the tubes. The tubes extend approximately vertically.

**[0044]** Figures 11a and 11b show a lamp using medium/high pressure discharge tubes 2' for treatment of one side of the patient P. This arrangement is similar to that shown in Figures 6a and 6b except that four parallel tubes are used and the lamp stands upright to illuminate one side of a standing patient P.

**[0045]** Figures 12a and 12b show a grid lamp 2" in an embodiment of the invention, positioned to illuminate part of the patient to be treated. Figures 13a and 13b show an alternative lamp comprising four such substantially coplanar grid lamps 2" arranged in a row, to illuminate the whole length of a patient.

**[0046]** Figures 14 and 15 show a lamp using medium/high pressure discharge tubes 2' according to any of the above embodiments. In Figure 14, the lamp is mounted at one end of a bed S so that its height above the bed S is adjustable, for facial treatment of a patient lying on the bed. In Figure 15, the lamp is mounted on a stand ST and is adjustable in height, for treatment of a selected part of a patient P lying on the bed S.

**[0047]** Figures 16 to 18 show a lamp comprising an array of parallel fluorescent tubes 2 for treatment of a sitting patient P. The arrangement of Figure 16 is used for treatment of the sole of the patient's foot or feet. The arrangement of Figure 17 is used for treatment of the patient's lower leg(s). The arrangement of Figure 18 comprises two flat arrays of such tubes, arranged on the underside and inner back surface of a desk-like structure D, for full-leg treatment of the patient. The desk-like structure D is advantageous for long treatments as it allows the patient to rest comfortably and read, eat or perform other activities on the desk top.

**[0048]** Figures 19a to 19c show a lamp comprising a medium/high pressure discharge tube 2', for treatment of one or both elbows. The lamp comprises a cuboid housing 4 having two similar apertures 22 on one face, to allow the elbows to be inserted into the housing 4. A medium/high pressure discharge tube 2' is positioned with the reflector, towards the bottom of the housing. Light from the tube 2' is concentrated onto the elbows of the patient P by the reflector 16.

**[0049]** Figures 20a and 20b show a lamp comprising medium/high pressure discharge tubes 2' for treatment of the face and/or scalp. The lamp has a front-facial portion 24, comprising a medium/high pressure discharge tube 2' and a reflector 16, for directing light onto the face of the patient P from the front. A scalp portion 26 and left and right side-facial portions 28a, 28b are attached by hinges to the front-facial portion 24, each portion comprising a medium/high pressure discharge tube 2' and reflector 16 for directing light onto the scalp, left side of the face and right side of the face respectively. The front-facial portion 24 is slideably attached to a stand ST for vertical adjustment to the head height of the patient P, preferably when sitting.

**[0050]** Figure 21 shows a lamp similar to that of Figures 20a and 20b, except that it is arranged for facial and/or scalp treatment of a patient P when lying down. The vertical support is mounted on a bed S, instead of being free-standing, and the lamp is rotated by 90° so as to correspond to the position of the patient's head when lying down.

**[0051]** The above embodiments are described purely by way of example and variants thereof may fall with the spirit and scope of the present invention as defined by the following claims.

# Claims

1. A light source for therapy or diagnosis of a patient, comprising a non-planar array of substantially straight discharge tubes arranged to emit light substantially in the visible spectrum at an intensity of at least 3 mW/cm<sup>2</sup> on the patient.
2. A light source as claimed in claim 1, wherein the tubes are fluorescent tubes.
3. A light source as claimed in claim 1 or claim 2, wherein the tubes are arranged to emit light of wavelengths substantially confined within the range 350 to 500 nm.
4. A light source as claimed in claim 3, wherein the tubes are arranged to emit light of wavelengths substantially confined within the range 400 to 450 nm.
5. A light source as claimed in any preceding claim, wherein the tubes are arranged along a surface curved perpendicular to the length of the tubes.
6. A light source as claimed in claim 5, wherein the tubes are mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.
7. A light source as claimed in claim 6, wherein the housing is moveable along the length of the patient so as to irradiate a selected part of the length of the patient.
8. A light source as claimed in claim 5, wherein the tubes are mounted on the curved inner cylindrical surface of a housing dimensioned so as to irradiate only the lower half of a standing patient.
9. A light source as claimed in claim 5, wherein the tubes are mounted on the curved inner surface of a housing dimensioned so as to allow a patient to stand within the housing such that substantially the whole length of the patient's body is irradiated.
10. A light source as claimed in claim 1 or claim 3, wherein the tubes are arranged on at least two planar surfaces set at an angle to one another.
11. A light source as claimed in claim 10, wherein the tubes are mounted on the underside of a substantially horizontal surface under which the patient's legs rest when the patient is in a sitting position, and on a substantially vertical surface facing the patient's lower legs when the patient is in a sitting position.
12. A light source as claimed in claim 10, wherein the tubes are mounted on a first substantially planar member and on a second substantially planar member attached by a moveable joint to the first member.
13. A light source as claimed in claim 12, wherein the first planar member is arranged to irradiate the face of a patient from the front.
14. A light source as claimed in claim 12 or claim 13, wherein the second planar member is arranged to irradiate the scalp of a patient.
15. A light source as claimed in claim 12 or claim 13, wherein the second planar member is arranged to irradiate the face of a patient from the side.
16. A light source for therapy or diagnosis of a patient, comprising one or more discharge lamps arranged within a housing, an aperture allowing a part of the patient's body to be inserted into the housing, and a concave reflector mounted within a housing and arranged to concentrate light from the one or more lamps onto the part of the patient's body when inserted into the housing.
17. A light source for therapy or diagnosis of a patient, comprising one or more fluorescent grid lamps each comprising a tube having a plurality of folds in the same plane.
18. A light source for therapy of a patient, comprising at least one medium/high pressure discharge lamp and a housing arranged to allow a part of the patient to be brought into close proximity to the at least one medium/high pressure

discharge lamp such that light therefrom impinges on said part of the patient with an intensity of at least 3 mW/cm<sup>2</sup>, the light having a bandwidth of less than approximately 160 nm.

19. A light source according to claim 18, wherein the or each medium/high pressure discharge lamp has an arc length of at least 15 mm.
20. A light source according to claim 18 or claim 19, wherein the or each lamp is a medium pressure lamp.
21. A light source according to claim 20, wherein the lamp contains mercury vapour.
22. A light source according to claim 21, wherein the lamp further contains a vapour of one or more elements selected from a group comprising gallium, thallium, cadmium, indium and lead.
23. A light source according to claim 22, wherein the lamp contains a vapour of one or more elements selected from a group comprising cadmium, mercury, caesium, zinc, thallium and potassium.
24. A light source according to claim 23, wherein the lamp contains a rare gas.
25. A light source according to claim 24, wherein the rare gas consists of one or more of a group comprising neon, argon and krypton.
26. A light source according to claim 18 or claim 19, wherein the or each lamp is a high pressure lamp.
27. A light source according to claim 26, wherein the lamp contains sodium vapour.
28. A light source according to claim 27, wherein the lamp further contains xenon.
29. A light source according to claim 27, wherein the lamp further contains mercury.
30. A light source according to any preceding claim, wherein the intensity fluctuation across the treatable area of the patient is approximately 10% or less.
31. A light source according to claim 30, wherein the intensity fluctuation is approximately 6% or less.
32. A light source according to any one of claims 18 to 31, including a substantially regular array of similar said lamps.
33. A light source according to any preceding claim, including a diffuse reflecting surface arranged to reflect light towards the patient.
34. A light source according to any of claims 18 to 32, including a housing containing said one or more lamps, and an aperture allowing light from the one or more lamps onto the patient.
35. A light source according to claim 34, wherein said aperture has a transparent or translucent cover.
36. A light source according to claim 35, wherein said cover is arranged to filter part of the output spectrum of the one or more lamps.
37. A light source according to claim 36, wherein the cover comprises or includes a detachable filter.
38. A light source for therapy or diagnosis of a patient, comprising a plurality of low pressure discharge lamps mounted within a housing allowing light from the lamps to impinge on the patient, and a transparent or translucent cover over the aperture, the cover comprising or including a detachable filter.
39. Use of a light source according to any preceding claim in the treatment of superficial skin conditions.
40. Use according to claim 39, wherein the treatment is for cosmetic purposes.
41. Use of a light source according to any one of claims 1 to 38 in the treatment of one or more of: actinic/solar

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keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, psoriasis, eczema, nevus sebaceous, viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata or hirsutism.

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**42.** Use according to claim 41, wherein the condition is superficial.

**43.** Use according to any one of claims 39 to 42 in photodynamic therapy.

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**44.** Use according to claim 43, wherein the affected area of the patient is treated with PpIX.

**45.** A method of cosmetic treatment of a human or animal body, comprising:

applying a photosensitizer to the area to be treated, and

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illuminating the area with light from a light source according to any one of claims 1 to 38.

**46.** A method of medical treatment of a human or animal body, comprising:

applying a photosensitizer to the area to be treated, and

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illuminating the area with light from a light source according to any one of claims 1 to 38.

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Fig. 1

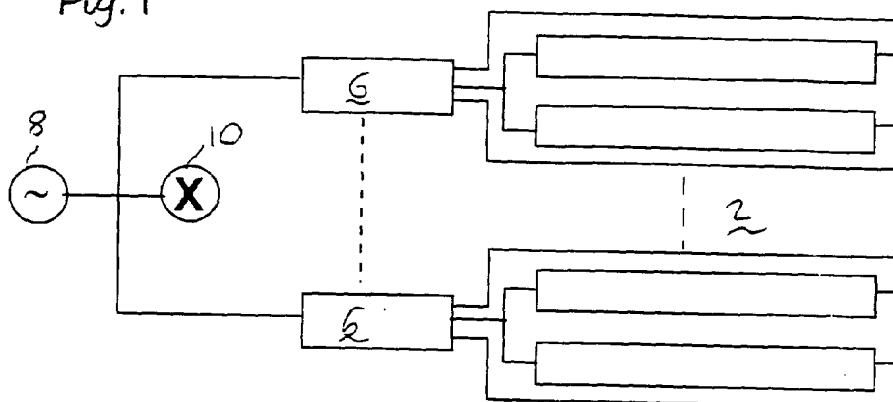


Fig. 2

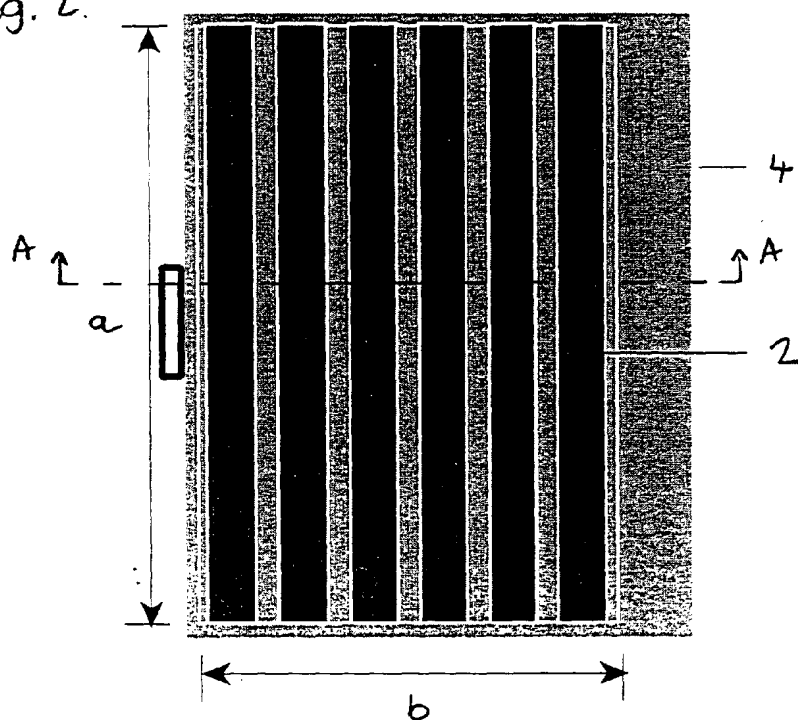


Fig. 3

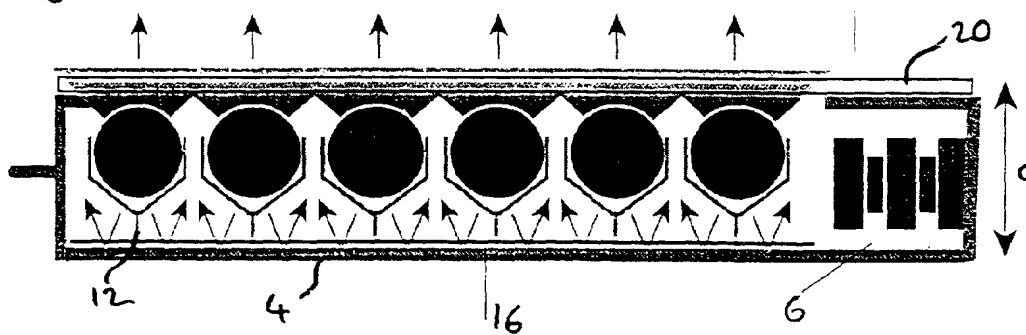


Fig. 4

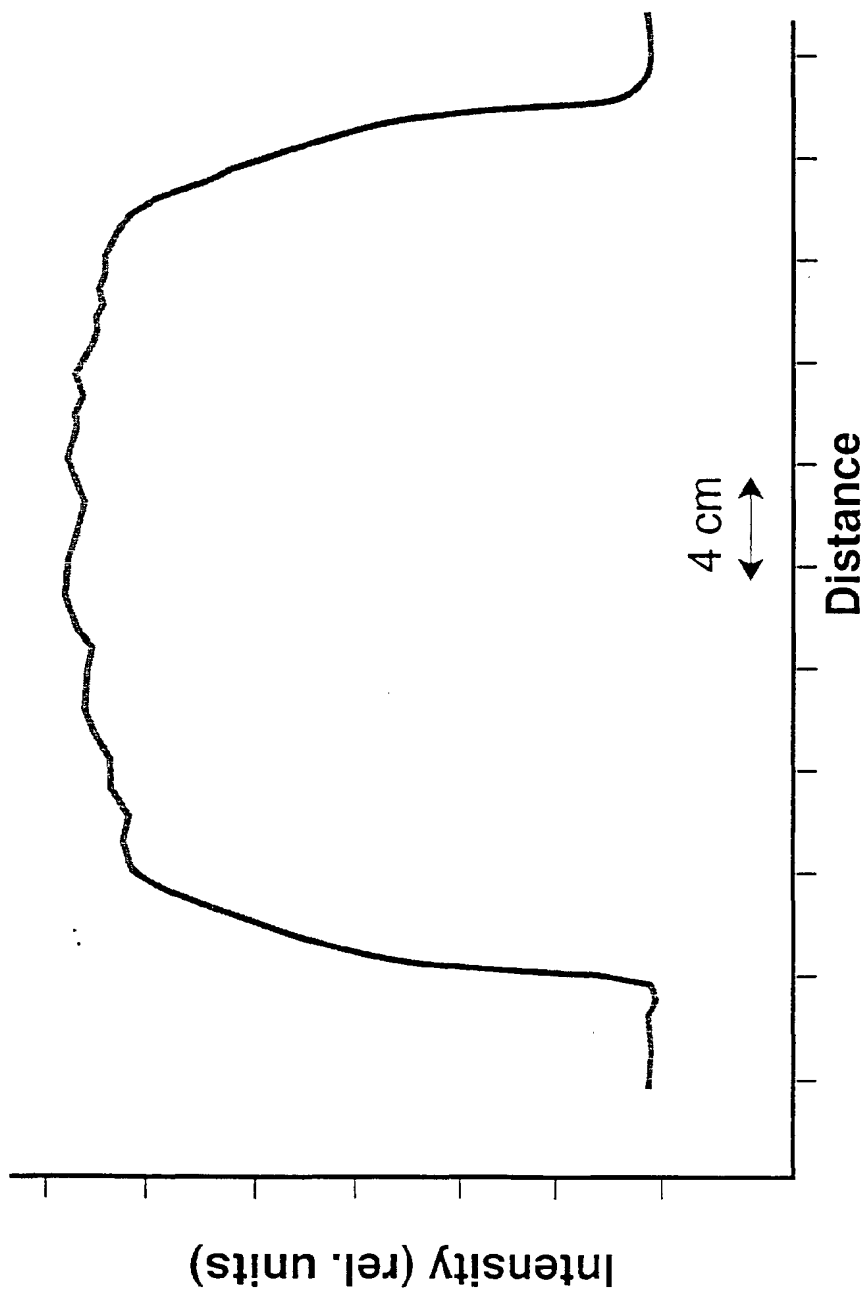


Fig. 5

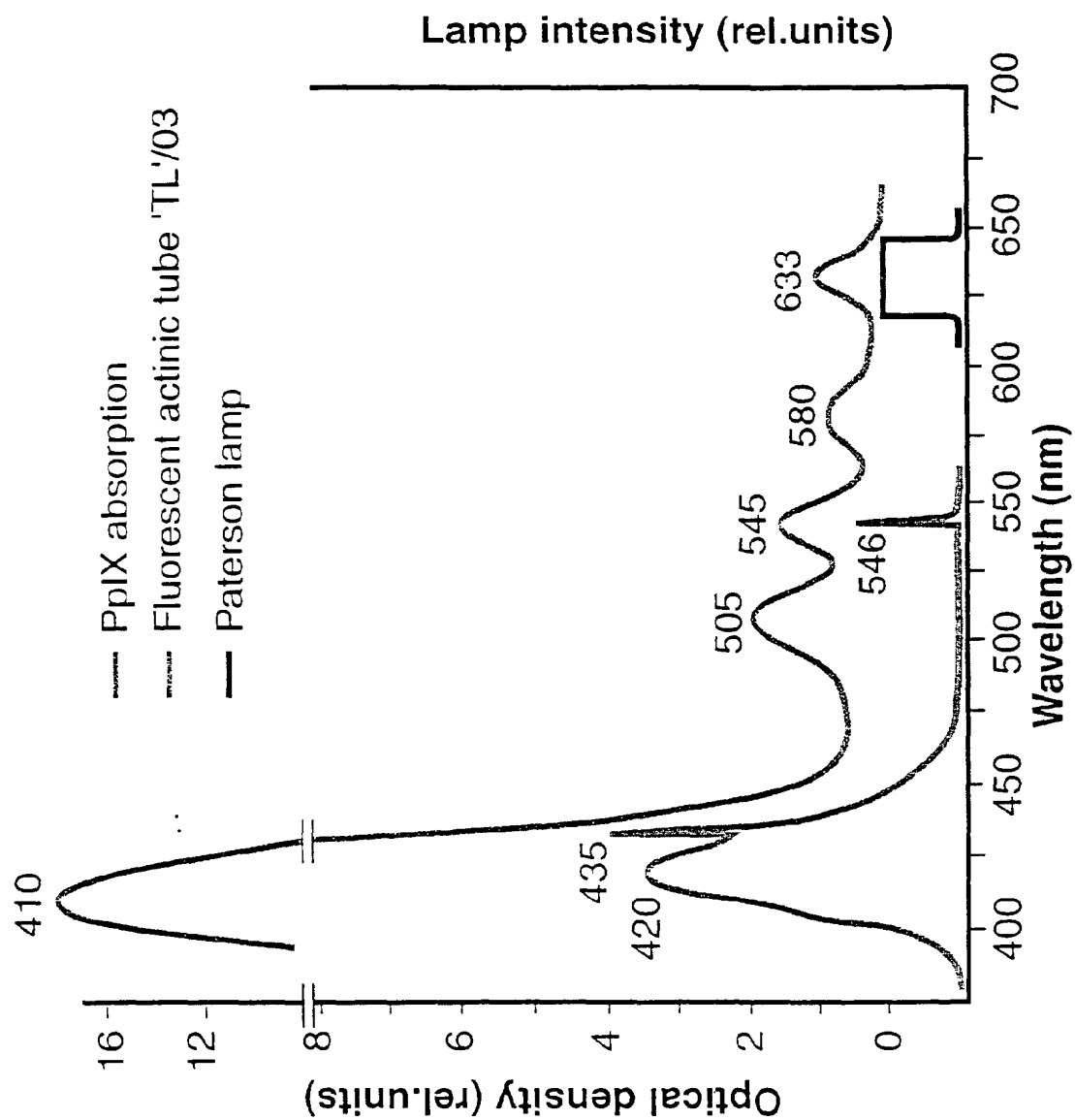


Fig. 6a

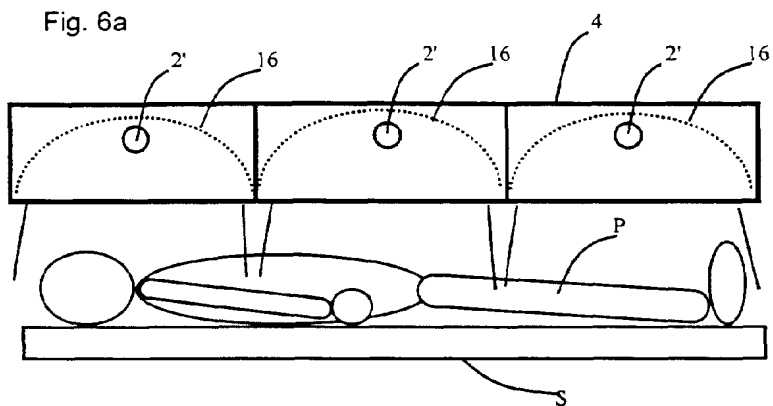


Fig. 6b

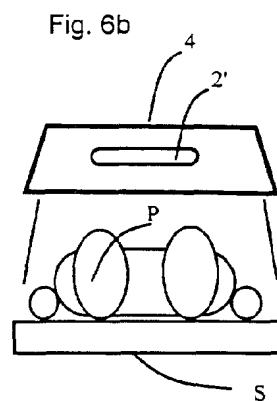


Fig. 7a

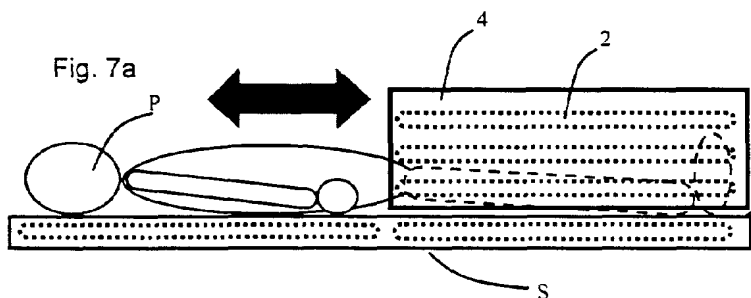


Fig. 7b

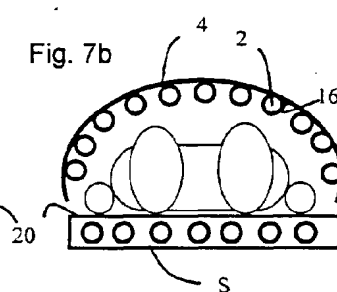


Fig. 8a

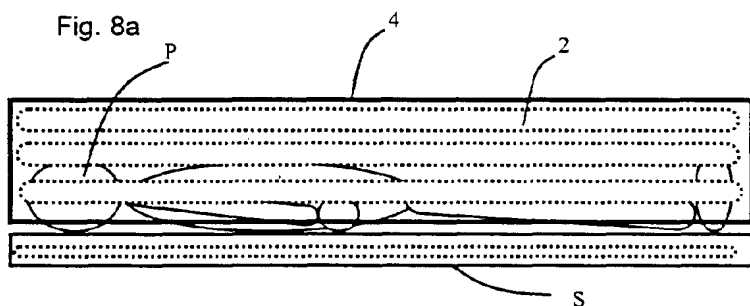


Fig. 8b

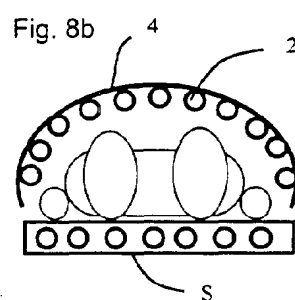




Fig. 9a

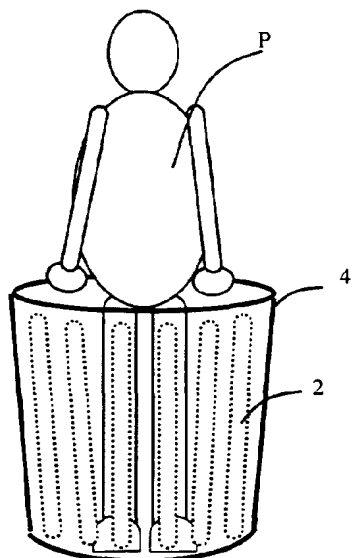


Fig. 9b

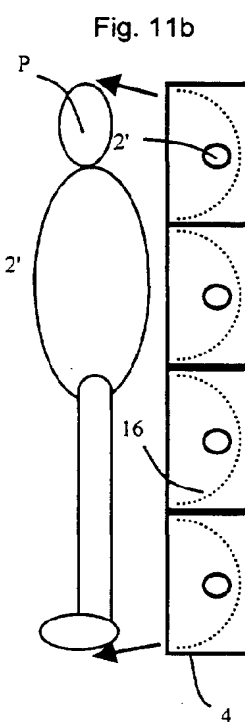
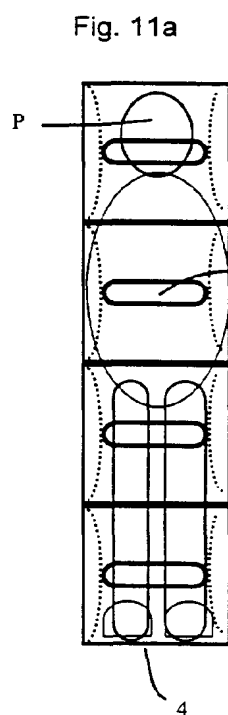
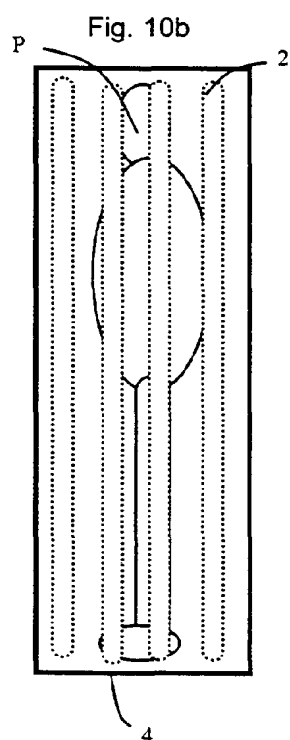
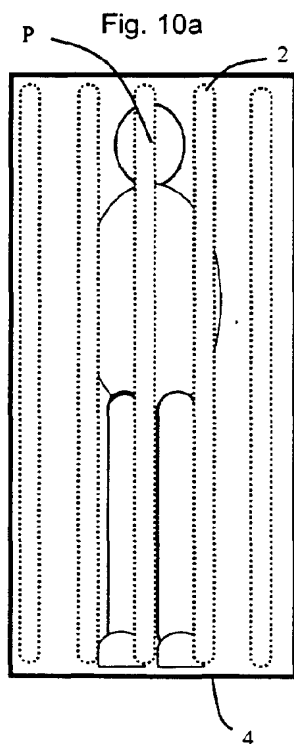
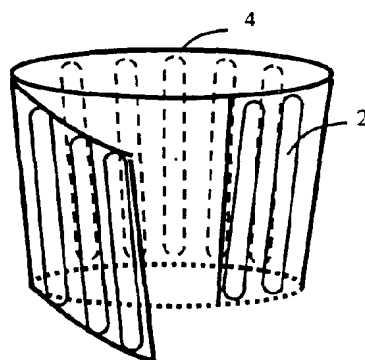


Fig. 12a

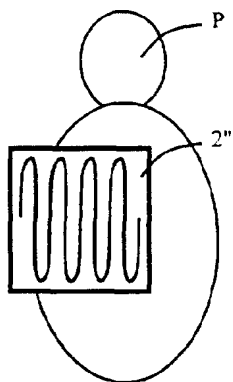


Fig. 12b

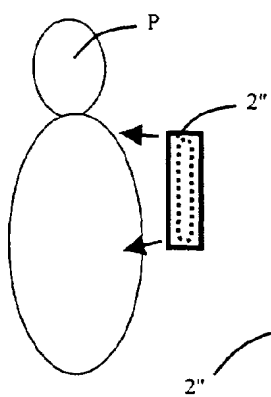


Fig. 13a

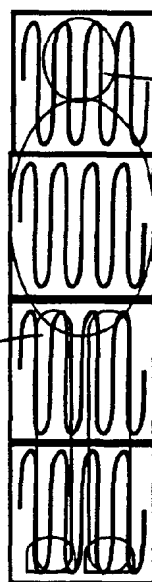


Fig. 13b

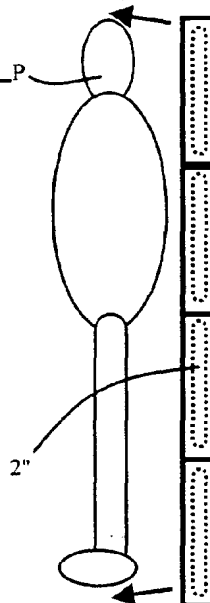


Fig. 14

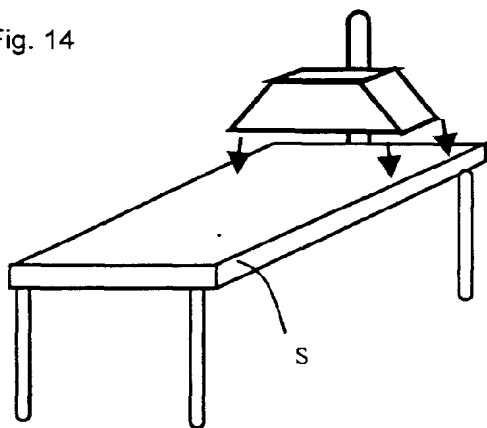


Fig. 15

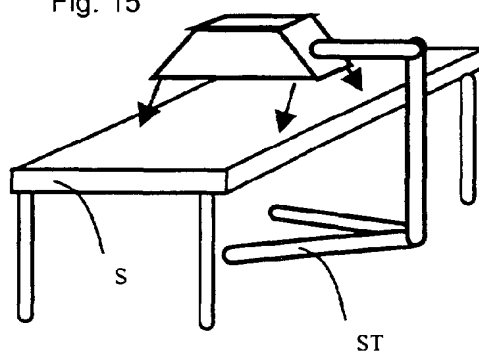


Fig. 16

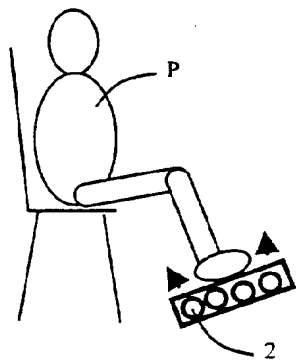


Fig. 17

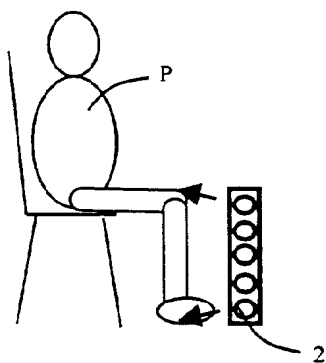


Fig. 18

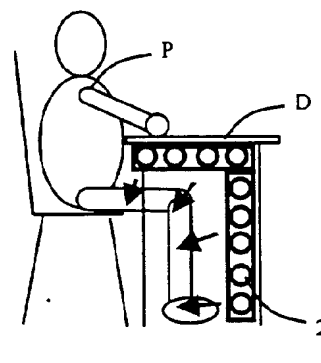


Fig. 19a

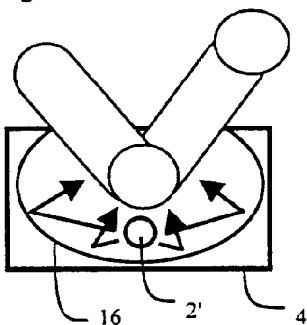


Fig. 19b

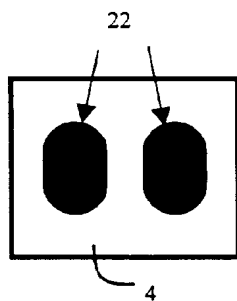


Fig. 19c

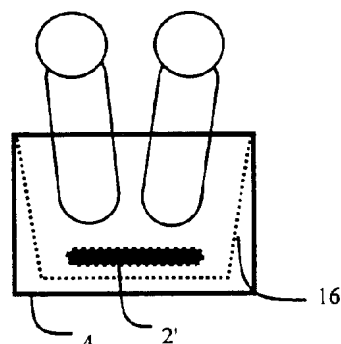


Fig. 20a

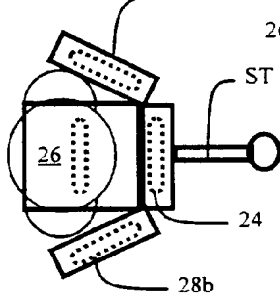


Fig. 20b

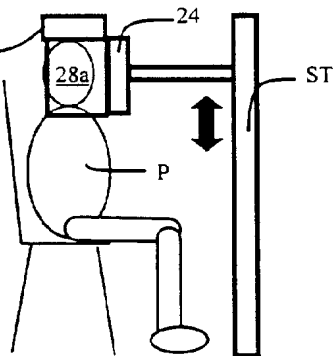
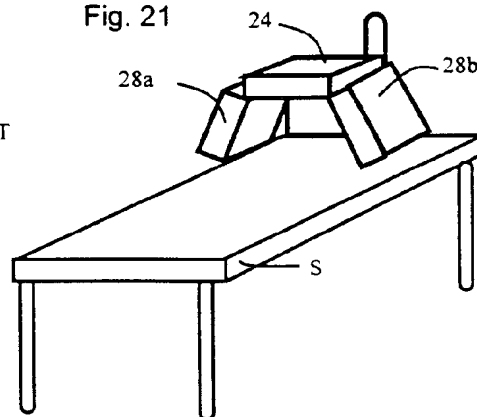


Fig. 21





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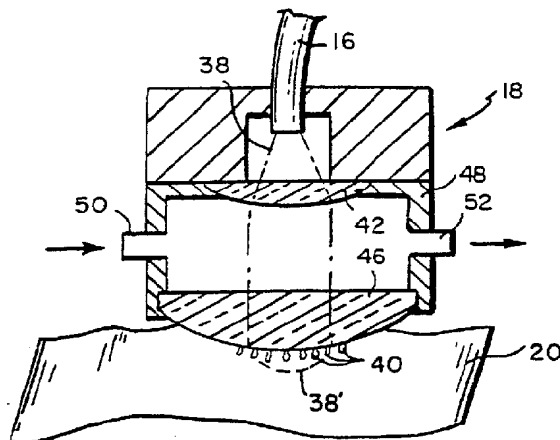
Remarks:

This application was filed on 28 - 03 - 2002 as a  
divisional application to the application mentioned  
under INID code 62.

(54) **Hair removal method using optical pulses**

(57) A method for simultaneously effecting the removal of multiple hairs from a skin region by using light energy to destroy hair follicles in the region is disclosed. Light energy is applied to the region through an applicator which converges the light energy to enhance destruction of desired portions of the follicles, is preferably pressed against the skin region to deform the upper layers of the skin reducing the distance from the skin sur-

face to portions of hair follicles which are to be destroyed, including the bulge and papilla of the follicles, and which applicator is preferably cooled to minimize or eliminate thermal damage to the epidermis in the region being irradiated. Parameters for the irradiation, including pulse duration, are selected to effect complete damage of desired portions of the hair follicles in the region with minimal damage to surrounding tissue and to the patient's epidermis.



**FIG. 2A**

**Description****Background**

5 [0001] This invention relates to methods for hair-removal using optical radiation.

[0002] Excess hair (hypertrichosis) and/or unwanted hair are common dermatological and cosmetic problems, and can be caused by heredity, malignancy, or endocrinologic diseases, for example hirsutism (i.e., excess hair due to hormones such as androgens). Hair can be temporarily removed using a number of techniques including wax epilation, depilatory creams, and, of course, shaving. Alternatively, hair can be more permanently removed using electrolysis; this process involves insertion of a current-carrying needle into each hair follicle, and is often painful, inefficient, and time consuming.

[0003] Optical-based methods, such as the use of laser light, have also been used for hair removal. U.S.-A-4 388 924, for example, describes irradiation of individual hair follicles using a laser; in this method, heating of the hair's root section causes coagulation in local blood vessels, resulting in destruction of the follicle and thus in removal of the hair. Related techniques, such as those described in U.S.-A-5 226 907, involve destruction of the follicle by first applying a light-absorbing substance to the region of interest, the light-absorbing substance migrating at least part-way into the follicle, removing the excess light-absorbing substance, and then irradiating the region to heat the substance and thus the follicle to cause destruction of the follicle.

[0004] The above prior art techniques suffer from a number of limitations. First, techniques for irradiating an individual hair follicle are time consuming and therefore are generally not practical for removing hairs other than from a very small region or from a region having few hairs situated therein. The procedure can also be painful, particularly if a needle-like element is inserted into the hair follicle to facilitate light energy reaching the bulge and the root or papilla, parts of the hair follicle which must be destroyed in order to prevent regrowth of the hair. Where the irradiation source is not inserted into the follicle, it is difficult to get sufficient energy to the required portions of the follicle to result in destruction thereof without also causing significant damage to the surrounding tissue and thus causing pain and injury to the patient.

[0005] While the technique of the latter patent is advantageous in that it permits a number of hairs in a given region to be simultaneously removed, it is difficult with this technique to get the light-absorbing substance or chromophore deep enough into the follicle to effect destruction of the papilla. Further, this technique results in substantial energy being applied to and absorbed by the epidermis and other skin layers in the region being treated, with significantly reduced energy reaching the root or papilla of the follicle. Total destruction of the follicle, and therefore permanent, or at least long term, hair removal is therefore difficult to achieve, particularly without risking damage to the epidermis and other layers of skin within the region.

[0006] A need therefore exists for an improved technique for performing hair removal which facilitates optical energy reaching the bulge and base, or root of hair follicles in a region while minimizing damage to the epidermis in the region, thereby minimizing patient discomfort and potential adverse side effects from the treatment.

**Summary Of The Invention**

[0007] The present invention provides in a first aspect, a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:

- (a) placing an applicator in contact with the skin surface in the said region; and
- (b) applying optical radiation of a selected wavelength and of a selected fluence through the applicator to the said skin region, for a predetermined time interval, pressure being applied to the applicator during steps (a) and (b) so as to cause the applicator to deform the skin region thereunder.

[0008] In a second aspect, the invention provides a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:

- (a) utilizing an applicator to form a fold of the skin in the said skin region, the applicator being in contact with the skin surface in the said skin region on two substantially opposite sides of the fold; and
- (b) applying optical radiation of a selected wavelength and of a selected fluence through the applicator to the said skin region for a predetermined time interval, the optical radiation being applied to the said two substantially opposite sides of the fold.

[0009] In a third aspect, the invention provides a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:

(a) applying optical radiation of a selected wavelength and of a selected fluence to the said skin region for a predetermined time interval; and

(b) cooling the skin surface in the said skin region to a selected depth prior to step (a) and during step (a), the said selected fluence and the said predetermined time interval being selected such that there is at most minimal heating of skin in the said skin region to the said selected depth, while causing sufficient heating of at least one of hairs and follicles below the said selected depth to at least damage the hairs and follicles without causing significant damage to tissue surrounding the follicles, whereby at least one of the hairs and follicles is heated and damaged without causing significant damage to the skin surface in the said skin region up to the said selected depth.

**[0010]** In a fourth aspect, the invention provides a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:

(a) positioning an element over the skin surface in the said skin region through which optical radiation may be passed; and

(b) applying optical radiation of a selected wavelength and of a selected fluence through the element to the said skin region for from 2ms to 200 ms.

**[0011]** The applicator is preferably pressed against the skin surface, thereby reducing the distance from the applicator to the papilla of the hair follicles and facilitating destruction thereof. Preferably, the skin surface in the skin region is cooled to a selected depth during the applying of optical radiation to the skin region and/or prior thereto. This allows the papilla of the hair follicles to be significantly heated without damage to the skin surface in the skin region up to the selected depth.

**[0012]** In preferred embodiments, an applicator is utilized to cool the skin surface in the skin region to the selected depth and the selected depth is preferably at least equal to the depth of the epidermis layer of the skin (i.e. the layer of the skin closest to the skin surface). This may for example be accomplished by cooling at least the surface of the applicator in contact with the skin surface, such cooling preferably being accomplished both before and during the irradiation of the skin. The cooling of an applicator is accomplished by passing a cooling fluid through the applicator. Further, it is also preferred that irradiation of the skin surface not be performed until the skin region has been cooled to substantially the selected depth. In preferred embodiments, cooling is performed both before and during irradiation, and the selected flux and predetermined exposure time (i.e., time interval for irradiation) are selected such that there is at most minimal heating of skin in the skin region to the selected depth, while there is sufficient heating of hairs and follicles below the selected depth to at least damage the hairs and follicles without causing significant damage to tissue surrounding the follicles. A preferred time interval for irradiation is 2 to 100 ms.

**[0013]** An applicator is also preferably designed to converge optical radiation applied to the skin region, thereby further facilitating irradiation of the follicle papillas. An applicator can have a convex surface in contact with the skin surface, applying substantially uniform pressure thereto to deform the underlying skin surface. An applicator can be designed to form a fold of the skin in the skin region and to apply optical radiation to two substantially opposite sides of the fold. For example, an applicator may have a slot formed in the surface thereof in contact with the skin surface, with at least a portion of the skin region being drawn up into the slot and optical radiation being applied to the skin region from at least two opposite sides of the slot.

**[0014]** It is also desirable that a substantial refractive index match be maintained between an applicator and the skin surface in said skin region. Such refractive index match may be provided by a layer of refractive index matching substance between an applicator and the skin surface in a skin region and/or by forming an applicator of a material which at least for the surface in contact with the skin region has a refractive index which substantially matches that of the skin surface.

**[0015]** To facilitate hair removal, hairs in the skin region may be shaved prior to irradiation. However, it may be preferable to epilate the hairs in the skin region before irradiation. When hairs are epilated, destruction of the follicles can be facilitated by filling the follicles from which the hairs have been epilated with a substance which preferentially absorbs optical radiation at the selected wavelength being used for irradiation (i.e. a chromophore). Further, where only temporary hair removal is desired, this may be accomplished for a period of up to several weeks, relatively painlessly, by applying the chromophore to the area, which has been preferably pre-shaved, which chromophore migrates into the hair follicles to a depth of a few millimeters, roughly to the depth of the sebaceous gland. Low level irradiation applied through the applicator to the skin region will then result in the destruction of the hair without destroying the follicle.

**[0016]** An applicator suitable for use in practising hair removal in accordance with the invention may include an inlet through which optical radiation is applied to the applicator, a surface shaped to contact the skin surface in the skin region, an optical path from the inlet to the surface, which path is substantially transparent to optical radiation at the selected wavelength, an element in the optical path for converging the optical radiation as it leaves the applicator

through the surface and some means for cooling the surface to a temperature below that of the skin region. As indicated previously, the surface is preferably formed of a material having a refractive index which substantially matches, but which is not less than, the refractive index of the skin surface in the skin region. The element for converging the optical radiation can be a lens and the means for cooling can be a channel near the surface through which cooling water is passed. The surface of the applicator in contact with the skin may have a convex shape or the surface may have a slot formed therein, with the optical path leading to at least two opposite sides of the slot, and the applicator including a means for drawing at least a portion of the skin region into the slot, this means for drawing preferably includes a vacuum applying element.

## Brief Description Of The Drawings

### [0017]

Fig. 1 is a perspective view of a laser-based hair-removal device for use in methods according to the invention; Figs. 2A and 2B are cross-sectional views of an irradiating unit or applicator suitable for use in a method of this invention, the applicator receiving, respectively, light from a fiber optic or fiber optic bundle, and from a mirror assembly;

Figs. 3A, 3B, and 3C are, respectively, an expanded, cross-sectional view of the contact device of the irradiating unit in direct contact with a hair-containing skin region, a cross-sectional, cut-out view showing the back-scattered optical fields at the contact device/epidermis interfacial region, and a cross-sectional cut-out view showing thermal transport at the interfacial region;

Fig. 4 is a plot showing the optical absorption spectra of melanin, hemoglobin, oxygenated hemoglobin, and water; Figs. 5A and 5B show, respectively, the time and spatial profiles and the preferred optical field used during the hair-removal process;

Fig. 6 is a plot of the computer-generated optical intensity as a function of skin depth for different optical fields;

Fig. 7 is a photograph showing skin regions of a patient three months after being treated according to the hair removal method of the invention;

Figs. 8A, 8B and 8C are oscilloscope traces showing, following irradiation, the time-dependent temperature responses of, respectively, dry black hair, wet black hair, and live skin surrounding the black hair sample;

Fig. 9 is a plot showing the temperature rise as a function of laser pulse energy for dry hair (DH), wet hair (WH), and skin (S) samples of eight different patients;

Fig. 10A is a partial cross-sectional view of an applicator being used to practice an alternative embodiment of the invention wherein epilation and filling of empty follicles with a chromophore are performed before irradiation; and Fig. 10B is a cross-sectional view of an applicator for an alternative embodiment being used for hair removal.

## Detailed Description

[0018] Referring to Fig. 1, an exemplary laser-based hair-removal system 10 includes a light source 12, which may, for example, include one or more lasers for generating the irradiating field. The light source 12 may be optically coupled to a series of beam-manipulating optics 14 which, in turn, may be coupled via a fiber optic cable 16 (or other fiber optic device) to the irradiating unit or applicator 18. During the hair-removal therapy, the light source is powered by a voltage and current supply 19, and delivers a beam of light through the optics 14 and fiber optics 16 to the irradiating unit or applicator 18. The field is then delivered to a region 20 of a patient 22 (positioned, for example, on a table 25, a chair, or other suitable positioning element depending on the location of the region 20 on the patient's body) resulting in hair removal from the region 20. Once the desired region is treated, the irradiating unit can be easily moved along the patient 22, as indicated by arrows 27, and used to treat subsequent regions.

[0019] The spatial and temporal properties of the optical field determine the efficacy of the hair-removal process, and some of these properties may, if desired, be adjusted using a series of controls 24, 26, 28 located on various components of the hair-removal system 10. For example, using controls 24 located on the power supply, the optical intensity and pulse repetition rate of the irradiating field can be controlled by adjusting parameters such as the voltage, current, and switching rate for the laser's power supply. Other properties of the field, such as the wavelength and pulse duration, may be varied by controls 26 which adjust components (e.g., gratings, mirror or filter positions, shutters, or pulse-forming means) of the light source 12; however, for preferred embodiments wavelength would not be adjusted. Similarly, controls 28 can be used to adjust the modulating optics 14, resulting in control of properties such as mode quality, beam diameter, and coupling of the irradiating field into the fiber optics 16. All controls may be adjusted by hand; and the system may also be operated (i.e. the laser turned on) by hand or, alternatively, by using a foot pedal 30 connected to the system 10.

[0020] In alternate embodiments, the light source, coupling optics, and irradiation unit may be encompassed in a

single, hand-held device. In this case, the light source is preferably an array of diode lasers coupled directly to the irradiating unit, and is powered by a small external power supply. The compact nature of this type of optical system allows for a more controllable, maneuverable device, and additionally obviates the need for fiber optic delivery systems.

**[0021]** In order to effectively destroy the irradiated hair follicles without causing damage to the surrounding skin, the light field supplied by the system 10 and the irradiating unit 18 is designed to maximize the amount of light-induced heat deposited in the hair follicles, while reducing the degree of injury to the surrounding skin. It is preferred, for example, to deliver sufficient optical energy to several "target" regions on the hair follicle; radiation delivered to these regions results in complete and localized destruction of the follicles.

**[0022]** Prior to treatment, the region to be treated may be shaved in order to facilitate irradiation of the follicles. Alternatively, as will be discussed later, hairs in the region may be epilated and a chromophore may be applied to region 20, which chromophore migrates into the empty follicles. Excess chromophore may then be removed from the skin surface prior to irradiation. Prior to treatment, an anesthetic may also be injected locally or applied to the skin surface and following treatment, patients may be treated with topical antibiotic ointments.

## Mechanical Structure

**[0023]** With reference now to Figs. 2A and 2B, the applicator or irradiating unit 18 of the hair-removal system allows delivery of the irradiating field 38 to hair follicles 40 located in the region 20. As shown in Fig. 2A, the field 38 may be delivered to the irradiating unit 18 using a fiber optic cable 16 (or other fiber optic device) containing one or more fibers or fiber optic bundles. In this case, after exiting the waveguide, the field 38 is typically spatially dispersed, and is preferably collected and roughly collimated using a plano-convex lens 42. Alternatively, as shown in Fig. 2B, the field may be delivered to the irradiating unit using, for example, one or more reflecting mirrors 44. This allows the field 38 to be roughly collimated prior to impinging on the lens 42. Depending on the focal length of the lens 42 and the mode quality of the irradiating field, the field is preferably condensed using, e.g., a plano-convex lens as shown in the figure. After passing through this optic, the beam then impinges on a lens or contact device 46 which is placed in contact with the skin region 20. The optical and mechanical properties of the contact device 46 are chosen to allow efficient coupling of the optical radiation into the skin region (resulting in a delivered field 38) and the thermal properties of the contact device are chosen to allow efficient coupling of heat from the skin region. Once delivered, the field is used to irradiate, heat, and then destroy the hair follicles 40. The contact device 46, in addition, is used to couple light and heat out of the superficial skin layer (i.e., epidermis) of the irradiated region. This allows the light-absorbing pigment (i.e., melanin) contained within the deep part of the hair follicles to be irradiated and selectively heated, permitting permanent destruction of the follicle, while potentially deleterious optical and thermal energy are simultaneously conducted out of the overlying skin layers. Thus, multiple hair follicles can be destroyed, permanently removing hair from the skin region without causing substantial pain or injury to the patient. The destroyed follicles are ultimately removed by the body.

**[0024]** Both the lens 42 and contact device 46 are preferably disposed in a housing 48 containing both entrance 50 and exit 52 ports for fluids such as cooling water and pure gas (i.e., nitrogen to prevent condensation on the lens) to flow into and out of; fluids may be used, for example, to cool the contact device 46, which, in turn, cools the skin surface. Alternatively, the housing 48 may include an electrically controlled cooler in order to provide accurate control over the temperature of the contact device 46. Preferably, when cooling means are used, the temperature of the surface layer or epidermis of the skin is reduced to between 4-15°C. In addition, in this case, it is preferred that a short time period (e.g., about 1 second) be allowed to elapse before irradiation in order to ensure that the epidermis is adequately cooled. An external casing 39, as indicated in Fig. 2B by the dashed line, or a fiber-coupling housing 37, as shown in Fig. 2A, may be used to connect the light-delivering means to the housing 48.

**[0025]** With reference now to Fig. 3A, the contact device 46 is preferably formed into a lens shaped in order to converge the irradiating field, preferably near the base of the hair follicles 40. In order to converge light, the contact device must be optically transparent at the irradiating wavelength, and preferably has a biconvex or plano-convex lens shape, preferably with an f number less than or equal to f/1.0, and a focal length of between about 0.5 and 2 cm. Control over the surface shape of the contact device allows the converged light field 38' to simultaneously irradiate various target portions of the hair follicle, resulting in efficient destruction. Typically, each irradiated hair shaft has a diameter of about 75 microns, with the entire follicle having a diameter of about 200 microns. After passing through the contact device 46, the light field 38' is preferably converged through the epidermis 56 of the skin layer (having a thickness, e.g., of about 0.1 mm) and is condensed in the dermis 58 near the papillae 54 of the follicles 40. Because dermal thickness varies greatly over the body, the papillae may be superficial (as in, e.g., the eyelids and scrotum), but for most areas of interest (e.g., the face, axillae, and legs) the papillae are located at depths of approximately 4 to 7 mm beneath the epidermal surface. Located a few tenths of a millimeter below the papillae are neurovascular bundles 60 which serve the metabolic and other needs of a hair matrix, the region of rapidly growing keratinizing cells, located in the papilla, which produce the hair shaft 55. The matrix, papilla, and the corresponding vascular bundle, as well as the bulge near the center of the follicle, represent the follicular targets to be irradiated/destroyed. Preferably, during



irradiation of these regions, the field is pulsed, the pulse duration of the irradiation being kept short enough so that damage is localized to a small region of dermis (typically within about 0.2 mm) surrounding each follicle in accordance with the principles of selective photothermolysis. The extent of damage is preferably much less than half the distance between neighboring follicles (typically between 1 and 4 mm); if it is significantly greater than this, the light-induced injury may result in a third-degree burn.

**[0026]** In addition to providing a light converging function, a contact device 46 having a convex-shaped surface 62 allows efficient compression of the skin during contact. Compression of the dermis 58 located near the surface 62 of the contact device decreases the distance between this region and the papillae; depending on the force applied, the distance may be decreased by up to several millimeters. Because the radiation field 38' is scattered and correspondingly attenuated during propagation through the dermis, compression of the skin results in bringing more light to the deep portions of the hair follicles for more efficient light-induced heating of the papilla. In addition, compression of the dermis by the contact device using a pressure greater than the patient's blood pressure forces light-absorbing blood out of the irradiated region (indicated during treatment by a whitening of the skin in the pressurized region). This reduces absorption of the optical field, resulting in more efficient delivery of light to the follicular target regions. Pressure applied using a contact device having a convex surface results in a relatively uniform displacement of blood from the skin region. A contact device having this shape is therefore preferred to a flat device, which tends to produce regions having center portions which are not entirely blood-free.

**[0027]** In alternate embodiments, the contact device may be mounted in the housing in a spring-loaded fashion so that it may be forced against the skin surface with an adjustable pressure. In addition, in this embodiment, the spring mechanism may be attached to a sensor and readout device so that the exact pressure applied to the skin surface can be accurately monitored and/or controlled.

**[0028]** When forced against the skin, the contact device 46 allows optical radiation to be coupled into and out of the epidermis. With reference now to Fig. 3B, the refractive index ( $n_{CD}$ ) of the contact device 46 should be approximately matched to that ( $n_{EP}$ ) of the epidermis 56, which is approximately 1.55. Because light travelling from one refracting medium (i.e., the contact device) to another (the epidermis) is reflected at the interface 57 separating the two regions by an amount related to the square of the refractive index difference, nearly index-matching allows efficient coupling of the irradiating field into the skin. Thus, a contact device composed of a material having a refractive index near 1.5 or somewhat greater allows the incident irradiating field to undergo minimal reflections (indicated in the figure by the arrow 64) at the epidermis/contact device interface 57. Similarly, as indicated in the figure by the arrows 66, optical fields within the dermis are back-scattered towards the epidermis due to diffuse reflectance. These back-scattered fields contribute to unwanted epidermal heating, and are easily coupled out of the skin using the index-matched contact device 46. This allows minimization of the light-induced damage to the epidermis 56, while allowing effective irradiation of the follicle target sites within the dermis. In preferred embodiments, in order to be substantially index-matched, the contact device is preferably formed of a high-density material such as sapphire ( $n_{CD} = 1.7$ ), fused silica ( $n_{CD} = 1.5$ ), or similar optically transparent glasses or plastics. In order to provide a convergent field entering the skin and to have the convex shape of the contact device as shown, it is advantageous to use sapphire, the slightly higher index of which facilitates the desired field convergence.

**[0029]** With reference now to Fig. 3C, in order to conduct heat away from the epidermis, it is additionally preferred that the contact device 46 be composed of a material having a high thermal conductivity ( $k_{CD}$ ) which is similar to that of the skin. This allows efficient transfer of heat (indicated in the figure by the arrows 68) from the epidermis 56, across the contact device/epidermis interface 57, and into the contact device 46. A high thermal conductivity, in addition, is necessary to minimize local heating effects that may occur at the interface 57, thereby reducing the chance of thermally induced damage or injury to the irradiated epidermis. As will be discussed later, this is particularly important when the contact device is cooled. Ideally, the thermal properties of the contact device and the time the contact device is applied to the skin before irradiation begins allow minimization of heating near the epidermis, but have little effect on heat deposited near the papillae of the hair follicle (shown in the figure as region 70). Materials having high thermal conductivities include sapphire ( $K_{CD} = 0.083 \text{ cal sec}^{-1} \text{ cm}^{-2} \text{ }^{\circ}\text{C cm}^{-1}$  along the C axis at  $30^{\circ}\text{C}$ ), fused silica ( $K_{CD} = 0.026 \text{ cal sec}^{-1} \text{ cm}^{-2} \text{ }^{\circ}\text{C cm}^{-1}$  along the C axis at  $30^{\circ}\text{C}$ ), as well as other high-density glasses and plastics.

**[0030]** In addition, in order to improve both optical (i.e., transmission of back-scattered light) and thermal (i.e., heat conduction) properties at the contact device/epidermis interface 57, it is desirable to apply to the skin a topical liquid or emollient, such as a lotion, water, alcohol, or oil, having a refractive index which is similar to that of the contact device 46 and epidermis. For example, application of an oil having a refractive index between that of the epidermis ( $n = 1.55$ ) and sapphire ( $n = 1.7$ ) minimizes optical reflection effects at the interface, thereby allowing more efficient transfer of light into the skin region from the contact device and of back-scattered radiation from the skin region. Also, a liquid allows for more efficient transfer of heat by conduction from the skin into the sapphire, thereby reducing the degree of damage or injury to the epidermis.

## Optical Properties

**[0031]** The temporal and spatial distribution of intensity for the irradiating optical field inside the skin ultimately determine the amount of heat deposited into the target regions of the hair follicle; these properties therefore can be selected and/or adjusted to optimize the hair-removal process. In particular, properties which affect the hair-removal process include the pulse energy, pulse duration, repetition rate (i.e., the time duration between subsequent pulses), wavelength, energy, exposure spot size, beam convergence as it enters the skin, and mode geometry (i.e., spatial extent and uniformity) of the optical pulse. These characteristics may be selected according to the pigment present in the hair and skin to be irradiated; preferably, each parameter is adjusted so that the temperature at each target site, immediately following irradiation, is elevated to between about 80 and 120°C. Heating the follicle to this temperature leads to permanent damage and subsequent removal.

**[0032]** Referring now to Fig. 4, the wavelength of the irradiating field is chosen to be resonant with the natural pigment (i.e., melanin) present in the target sites (i.e., the hair shaft, bulge, matrix, and papilla). The absorption spectra of melanin, water, hemoglobin, and oxyhemoglobin shown in the figure indicate the ability of these compounds to absorb optical radiation at different wavelengths; low absorption indicates that light at the particular wavelength will penetrate deeper in the absorbing media. In general, in order to selectively heat the target regions, the wavelength of the irradiating field is chosen to match the absorption spectrum of melanin, which basically absorbs light from about 200 to 1200 nm; conversely, the wavelength is mismatched to the absorption spectra of compounds contained in the skin, such as water and hemoglobin. Light having wavelengths between 680 and 1200 nm, a range indicated by the arrow 70 in the figure, is effectively absorbed by melanin while being relatively transmitted by both hemoglobin and water, and therefore can be used for selective heating of pigmented hair surrounded by white or lightly tanned skin. In particular, light in the range of 680 to 900 nm or 1000 to 1200 nm is preferred, as this radiation is strongly absorbed by melanin, and will not be absorbed by the bands present in water and in oxyhemoglobin near 950 nm. For patients with less melanin present in the hair follicles (e.g. with auburn or light brown hair), the shorter wavelengths in this region are preferable because of the higher absorption coefficient of melanin. In addition, other light-attenuating effects besides absorption, e.g., scattering of radiation, are also wavelength-dependent, and should be considered during selection of the optical field's wavelength. For example, in human skin, the penetration of light is partially determined by the transport scattering coefficient ( $\mu_s$ ), which decreases at longer wavelengths due to scattering in the dermis. For radiation at 1000 nm,  $\mu_s$  is about  $10 \text{ cm}^{-1}$ ; light propagating into the skin from a generally index-matched medium at this wavelength will therefore reach a maximum intensity at about 1 mm below the skin surface.

**[0033]** Sources generating visible or near-infrared light in the preferred range of 680-1200 nm include diode ( $\lambda >> 800\text{-}1000 \text{ nm}$ ), Nd:YAG and Nd:YLF ( $\lambda = 1064 \text{ and } 1053 \text{ nm}$ ), Ti:Sapphire and infra-red dye ( $\lambda >> 700\text{-}1000 \text{ nm}$ ), ruby ( $\lambda = 694 \text{ nm}$ ) and alexandrite ( $\lambda = 700 - 850 \text{ nm}$ ) lasers. Ruby, Nd:YAG and diode lasers (particular arrays of diode lasers) are preferred as these sources are commercially available, well-categorized, and can be manufactured on a small scale. Light sources of this type can be incorporated into compact hair-removal devices which, in turn, can be easily manipulated by the operator during hair-removal procedures.

**[0034]** The duration of the optical pulse can also be controlled in order to vary the heating of the hair follicle. Referring now to Fig. 5A, the optical pulses, indicated by the waveforms 74, 74', preferably have durations 76, 76' which allow the follicle to be heated for short periods of time. The pulse width is controlled to vary the heat conduction during the optical pulse, and thus the damage of the follicle and its immediate surrounding dermis; too little damage results in hair re-occurrence, while extensive damage may produce scarring in the irradiated region. Preferably, the pulse duration 76, 76' is between about 2 ms and 100 ms.

**[0035]** The exact pulse duration is dictated by the diffusion of heat in the skin, a process which roughly follows the heat diffusion equation relating the diffusion time  $t$ , diffusion distance  $d$ , and thermal diffusivity  $k$ , as discussed by in Welch, A.J. "The thermal response of laser-irradiated tissue", IEEE J. Quant. Electron. QE-21 (12), 1471-1481 (1984):  $t = d^2/4k$  ( $k$  for the human dermis is roughly  $1.3 \times 10^{-3} \text{ cm}^2/\text{sec}$ ). The time needed for extraction of heat from the epidermis during a laser pulse is approximately 2 ms, and the thermal relaxation time for a typical 200 micrometer hair follicle is approximately 40 ms. For light exposures longer than a few hundred milliseconds, too much thermal diffusion may occur during the exposure period, resulting in either inefficient destruction of the target regions of the hair follicle, excessive dermal damage, or both. Further, since most of the melanin (roughly two thirds) in the epidermis is in the lower portion of the epidermis, heating of the epidermis occurs primarily in the deeper portions thereof, and some time is required for this heat to reach the surface in order to be removed by the contact device 46. Therefore, since this time is at least 2 ms, this is the minimum suggested pulse duration, with a longer time, preferably at least 5 ms, being suggested to minimize epidermal damage. Further, depending on the laser utilized, each pulse could be in the form of a single continuous pulse as shown in Fig. 5A or in the form of a train of closely spaced pulses of shorter duration, the space between such closely-spaced pulses being much shorter than 5 ms.

**[0036]** For a given fluence, the intensity of the optical field is inversely related to the pulse duration; thus, when the pulse duration is below about  $10 \mu\text{s}$ , large optical intensities may result in undesirable modes of damage to surrounding

skin regions. In addition, short pulses may result in localized heat-induced "explosions" in the follicle which cause mechanical damage to the skin. In particularly preferred embodiments, the pulse has a duration or pulsewidth of about 2 - 100 ms. During this time period, thermal diffusion takes place over a distance of about 0.05 to 0.3 mm; damage confined to about this distance results primarily in destruction of the irradiated hair follicles, with little or no damage to the surrounding skin.

**[0037]** Optical pulses having well-defined and adjustable durations may be generated using known techniques. For instance, intra-cavity modulation of the light field using electro or acousto-optic Q-switching devices allows generation of pulses having temporal profiles which are typically Gaussian in shape. Pulses made using these methods are typically too short, however, having durations in the sub-microsecond range. Normal-mode pulses produced by flashlamp excitation of ruby, alexandrite, Ti:sapphire, or Nd:YAG lasers are preferred because these typically are high-energy pulses in the 0.1 - 10 ms pulse duration region. Alternatively, a continuous (i.e., time-independent) optical field emitted by a laser can be externally modulated using, for example, a mechanical shutter or electro-optic gate. Modulation using external methods allows the pulse width to be easily varied from a few hundred microseconds to several hundred milliseconds. Pulses generated using external modulation may also have "square wave" temporal profiles (as shown in Fig. 5A) which allow a more uniform optical field to be applied to the region of interest. However, external modulation is not used for currently preferred embodiments.

**[0038]** When a contact device is used to deliver the optical pulse, a time delay preferably exists between the time at which the contact device contacts the skin surface and the arrival of the pulse. This allows the entire epidermal layer 56 to be cooled significantly prior to irradiation, thereby increasing its damage threshold. Pain and damage to the epidermis are thus reduced and are further minimized by continuing to cool contact device 46 during irradiation so that heat continues to be removed from the epidermis. However, heating at lower levels where destruction of the follicles, and in particular the bulge and papillae thereof, is desired is not affected by the cooling performed either before and/or during irradiation.

**[0039]** In addition, the time duration between optical pulses (indicated in Fig. 5A by the arrow 78) may be adjusted in order to control the total amount and rate on average of heat deposited into the irradiated region. If repetitive illumination is required for destruction of the follicle, this time period is preferably constant and lies between several seconds and a few hundred milliseconds. Alternatively, for "single shot" illumination, this time period is selectively controlled by the operator. In this case, a single laser shot is delivered to the region of interest, and then the region is inspected by the operator for damage. If more radiation is required, additional laser shots can then be delivered to the region. Otherwise, the irradiation unit is translated and used to treat a separate region.

**[0040]** The spatial extent of the optical field is chosen to allow multiple hair follicles to be irradiated with a single laser shot. In addition, larger spot sizes are preferred because attenuation along the beam axis within skin due to scattering decreases as the beam radius,  $R$ , increases. Thus, wide-area beams allow more efficient delivery of optical radiation to the deep target sites. Referring now to Fig. 5B, the width 80 of the spatial profile 82 of the irradiating beam at the surface of the skin is preferably on the order of, and preferably much greater than, the depth of the target to be irradiated. Most preferably, the beam diameter is at least 8 mm. The area of the irradiating field is preferably between about 0.5 and 2 cm<sup>2</sup>, and is most preferably between 0.75 and 1 cm<sup>2</sup>. Because the beam is preferably converged, the spatial profile will be condensed as a function of depth before reaching a waist at a depth defined by optical scattering in the dermis. Preferably, as shown in Fig. 5B, the intensity across the beam diameter is roughly constant in order to provide a substantially uniform irradiating field.

**[0041]** Referring now to Fig. 6, following illumination, the intensity distribution of optical radiation (i.e., the  $y$  axis in the figure) as a function of skin depth (i.e., the  $x$  axis) is calculated using Monte Carlo-based computer simulations. The distribution is a function of the beam's spatial profile, the optical properties of the medium in contact with the skin. Although the plotted data is based on a computer simulation, and is thus only an approximate, the  $x$  axis units are estimated to be about 500 microns per tick mark. The first curve 90 shows the skin depth-dependent properties of an optical field originating from a small, collimated spot of 800 nm light in air. In this case, the majority of the optical intensity is distributed near the surface of the skin (indicated by the "0" point along the  $x$  axis), with the intensity dropping off rapidly at larger depths. A larger, collimated spot originating from air (curve 92) has a more evenly distributed skin depth-dependent intensity, although the majority of the light is still concentrated near the skin surface. Delivering a large, collimated radiation spot from a material having a refractive index of 1.5 (curve 94) results in a relatively uniform optical intensity in the first millimeter or so of the skin; at larger depths, this intensity starts to tail off with a relatively slow time constant. Finally, in the preferred embodiment, a large, spatially converging optical field from the  $n = 1.5$  refracting material has an intensity at the skin surface which increases to a maximum after propagating about a millimeter into the skin. The intensity then attenuates as a function of skin depth with a time constant slower than that exhibited by the curve 94. Thus, a field of this type can be used to effectively heat the target sites of the follicle, with reduced heating of the skin at the surface, thus reducing heat injury to the skin.

**[0042]** In the case where the illuminating laser generates a beam having a diameter less than the preferred values, it may be necessary to expand the beam prior to delivery to the irradiating unit. This may be done with conventional

telescoping optics, e.g., two-lens systems configured to first expand and then collimate the emitted beam. Alternatively, as shown in Fig. 2A, the irradiating field may be coupled into an optical fiber and then delivered to the irradiating unit. In this case, the emerging field is naturally dispersed due to the waveguide nature of the fiber, and is then collected by a collimating lens. Displacement of the lens from the fiber tip allows the irradiating beam's profile to be increased to the desired amount.

[0043] The fluence of the optical field will be varied according to the degree of pigmentation in the patient, and is preferably between about 10 and 200 J/cm<sup>2</sup> for each pulse; patients with darker hair will require lower fluence than patients with lighter hair. Most preferably, the pulse fluence of the irradiating field for pulses of about 1 ms duration is between 30 and 50 J/cm<sup>2</sup>. As described herein, in all cases, the fluence is adjusted in order to heat the target regions to the desired temperature of approximately 80 to 120°C. Moreover, the level of fluence may be increased as the pulse duration is increased in order to compensate for less efficient heating of follicles due to heat conduction during long pulses. It may be necessary to increase or decrease the optical fluence in order to heat the hair follicle to the desired temperature if the wavelength of the irradiating light field does not lie in the preferred spectral regions (i.e., 680-900 nm or 1000-1200 nm). In addition, in cases where the laser output is below the desired optical fluence, it may be necessary to amplify the individual pulses prior to irradiating the skin. Optical amplifiers, such as external optical cavities, may be used for this purpose.

[0044] Table 1, shown below, lists the preferred parameters of the optical fields used for hair removal. The value of each parameter depends on the amount of hair in the region of interest, the degree of pigmentation of the hairs, and the pigmentation of the surrounding skin of the patient.

Table 1 -

Preferred Optical Field Parameters		
Parameter	Range	Preferred Values
Wavelength	680 - 1200 nm	680-900, 1000-1200 nm
Pulse Duration	50 $\mu$ s - 200 ms	2 - 100 ms
Beam Area	>0.5 cm <sup>2</sup>	0.75 - 1.0 cm <sup>2</sup>
Pulse Energy	10 - 200 J/cm <sup>2</sup>	30 - 50 J/cm <sup>2</sup>
Optical Coupling	external n $\geq$ 1.4	n=1.5 to 1.7
Beam Convergence, At Skin surface	collimated or convergent	f#0.5 - 2

[0045] The invention will now be further described with reference to the following examples.

### Examples

[0046] In order to demonstrate the efficacy of a hair-removal method according to the invention, *in vitro* black-haired dog skin was exposed to light from the normal mode of a ruby laser at  $\lambda = 694$  nm with a pulse duration of 270  $\mu$ s and optical fluences of 40 J/cm<sup>2</sup>, 71 J/cm<sup>2</sup>, and 160 J/cm<sup>2</sup>.

[0047] The spatial extent of the beam (8 mm diameter at the skin surface) allowed irradiation of approximately 100 hairs with a single laser shot. Following irradiation, each skin region was examined histologically. Examination revealed that at the highest fluences, dermal damage consistent with scarring of the skin was evident, indicating that at the highest fluences, light-induced thermal damage was not selective to the hairs. In contrast, at the lower fluences, and particularly at 40 J/cm<sup>2</sup>, localized follicular damage was observed, with no noticeable damage occurring in the neighboring skin regions or dermis between hair follicles.

[0048] In a separate set of experiments, in order to show that the temperature increase within the irradiated hair is dependent on the degree of pigmentation, fresh human hair and skin samples having different colors were exposed using the hair-removal method described herein. The light source for all experiments was the ruby laser described above. Emitted light was first coupled into an enclosed beam-steering device containing several mirrors coated to have high reflectivities at 694 nm, and then delivered to an irradiating unit similar to that shown in Fig. 2B. The unit included a 5-cm plano-convex glass lens positioned at the proximal end of a water-cooled plexiglass housing. A sapphire contact device shaped as a 1-cm focal length lens was disposed at the distal end of the contact device, with the convex side touching the skin to allow compression during exposure as described above. Human skin was irradiated with an 8 mm diameter beam by pressing the cooled (4°C) contact device against the skin region of the patients, and then delivering a single laser shot. Each shot typically resulted in the simultaneous exposure of about 10 hairs.

**[0049]** The skin and hair of six adult patients having hair color ranging from red to black was irradiated and then observed. In each patient, eight treatment sites, each having an area of 10 cm<sup>2</sup>, were irradiated. In order to monitor destruction of the papilla, sites 1-4 were wax-epilated prior to exposure to laser light, while sites 5-8 were shaven prior to exposure. Each site then received an optical fluence of either 28 J/cm<sup>2</sup>, 42 J/cm<sup>2</sup>, or 57 J/cm<sup>2</sup>. Patients were seen in follow-up examinations one month and three months (and for some patients also one year) after exposure. As seen from the photographs of the exposed regions shown in Fig. 7 (i.e., regions A-C), hair regrowth after three months was minimal or non-existing in all cases compared to the shaved-but-untreated region (Region D), clearly indicating permanent damage to the hair follicle. In the figure, sites A-C were treated with decreasing energy from the laser. It is clearly evident that hair removal is relatively less pronounced in region C, treated with a fluence of 27 J/cm<sup>2</sup>. Region D, the control region, was shaven at the same day regions A-C were treated. In addition, histological specimens obtained from the treated sites revealed that damage occurred exclusively to the hair follicle, while the surrounding dermis was essentially spared. There was statistically significant loss of hair for all of the subjects in the laser-treated sites compared with unexposed, shaven control sites. At one year later, there was also significant permanent hair loss without any scarring.

**[0050]** A separate set of experiments permitting measurement of the time-dependent temperature characteristics of hair and skin samples were conducted using a pulsed photothermal radiometry (PPTR) apparatus. In these experiments, the ruby laser described above was used at lower fluences to provide optical pulses having an energy allowing heating, but not destruction, of the follicles. Output from the laser was focussed onto the samples of human hair and skin to provide a uniform excitation field. A New England Research, Inc. black-body radiation detector containing an amplified, liquid nitrogen-cooled HgCdTe detector was used to monitor time-dependent characteristics of the sample temperature, and a Gentec, Inc. laser energy meter was used to monitor the irradiating pulse. The output from both detectors was then amplified with a compensated 0-10 Mhz dc-coupled preamplifier, and then relayed to a digital oscilloscope for recording and storing the data.

**[0051]** Eight patients having various skin types and hair coloring ranging from red/blonde to black were studied. In general, the PPTR results indicated that following irradiation at 694 nm, black hair experienced a larger temperature rise than lighter brown hair, and that both of these specimens experienced higher temperature rises compared to red/blonde hair. In addition, following irradiation, type II skin had a lower temperature rise than type III or type IV skin.

**[0052]** Referring now to Figs. 8A-8C, in a particular example using a patient with black hair and white skin, time-dependent traces measured using the PPTR apparatus indicate that 400 ms after irradiation, both wet and dry black hair experience, respectively, temperature rises of about 7°C and 72°C (Figs. 8A and 8B) from a baseline temperature of 23°C, whereas the surrounding skin (Fig. 8C) undergoes a temperature rise of less than 1°C. The difference in the temperature rise and time-dependent decay characteristics of the wet hair is likely due thermal effects (e.g., the higher heat capacity of wet hair).

**[0053]** Referring now to Fig. 9, in all cases, the normalized temperature rises (i.e., the ratio of temperature rise to laser pulse energy) in the wet and dry hair follicles were significantly higher than those measured in the skin, indicating selective heating of the follicles using the method of the invention. Table 2, shown below, lists the hair and skin types of each patient in the study. The patient numbers in the table correspond to the patient numbers in Fig. 9.

Table 2 -

Patient Hair and Skin Types		
Patient	Hair	Skin Type
1	Red	II
2	Brown	III
3	Brown	II
4	Gray/black	III
5	Gray/Black	III
6	Dark Brown	III
7	Gray/Black	II
8	Black	III

#### Other Embodiments

**[0054]** Fig. 10A illustrates an alternative embodiment of the invention wherein the region 20 is epilated rather than

being merely shaved prior to treatment in accordance with the invention. A fluid solution or suspension 100 containing a chromophore may then be applied to the skin region 20, with the chromophore containing fluid migrating into the empty follicles and filling the follicles. "Capillary action" of the fluid/chromophore into the follicles is desirable and may be enhanced by providing a low surface tension between the fluid and skin, for example by using surfactants or solvents. The excess fluid/chromophore may then be removed from the skin surface by washing, wiping or stripping. During irradiation, the chromophore 100 in the follicle absorbs light and is heated and, along with the heating of the melanin of the follicle itself, results in significant heating of the follicle to destroy the portions thereof, including the bulge and the papilla, required to prevent regrowth of hair. The chromophore therefore must absorb light at the wavelength or wavelengths used for irradiation. Suitable chromophores might include a carbon particle suspension or a dye such as methylene blue or indocyanine green. Melanin itself in liposomal form might also be used. Since the chromophore is only in the follicles, this technique maximizes damage to the follicles while minimizing damage to surrounding tissue, and for this reason is a preferred way of practising the invention, especially for those with blond, red, light brown or other light colored hair. Except for the differences indicated above, this embodiment of the invention operates in the same manner described for earlier embodiments, including the cooling of contact device 46, the deformation of the skin in the region 20, and the preferred optical irradiation, with the exception that lower frequency may be allowed when using the chromophores.

**[0055]** Fig. 10B illustrates a device or applicator 46' is modified so as to simultaneously expose both sides of a skin fold, in accordance with an embodiment of the invention. This further increases the relative delivery of light to the deep portion of the follicles. In Fig. 10B, the contact device has for example an opening or slot 110 in the face of the applicator into which the area 20 of the skin may be drawn by for example vacuum or suction being applied to line 112 leading into the top of slot 110, the skin in slot 110 being formed into a fold 113. Radiation may be applied through a fiber-optic bundle 114 which divides to apply the radiation to lenses 116 on either side of slot 110. Cooling water may be flowed over the surfaces of lenses 116 through a line 118. Alternatively, two applicators similar to those shown for example in Fig. 2A or 2B can be positioned on opposite sides of a skin fold formed by clamping the skin region therebetween or by other suitable means.

**[0056]** The advantage of folding the skin as discussed for the above embodiments is that radiation is applied to a relatively thin section of skin from both sides. Thus, the papilla of a given follicle may be receiving radiation not only from the lens 116 on the side of slot 110 where the follicle is located, but also some radiation from the lens 116 on the opposite sides of the slot. Thus, energy applied to the papilla of each follicle is increased without increasing the energy at the surface, thus facilitating hair removal with less pain and injury. By making the slot 110 relatively narrow, pressure is applied to the skin on both sides of the slot, the skin being compressed between the walls of the slot. The advantages of compressing the skin, including removing blood therefrom and reducing the distance from the skin surface to the papilla, are thus also achieved by this embodiment of the invention. Clamping to form the fold would also apply pressure to the skin.

**[0057]** It may also be possible to utilize the invention for short term hair removal, to provide a shave lasting for perhaps one to two weeks. This is achieved by applying the fluid/chromophore to the region which is to be "shaved" which region has preferably been shaved using conventional techniques, but not epilated. In this case the chromophore can only migrate a few millimeters into the follicle, to for example the level of the sebaceous gland. Excess chromophore may then be removed, and the contact device utilized with relatively low level radiation to heat the chromophore, and destroy the hair surrounded thereby, without substantial damage to either the skin or follicle.

**[0058]** While cooling water has been shown to cool contact device 46, other cooling techniques may be utilized. For example, a low temperature gas or liquid gas may be passed over the contact device for cooling purposes or the contact device may be sufficiently cooled prior to use so that it can continue to perform the cooling function during irradiation without having a cooling medium passed thereover. Other cooling techniques known in the art may also be utilized.

**[0059]** Other embodiments are within the scope of the following claims. For example, the contact device may not be cooled or cooling of the epidermis may be performed without an applicator (for example cryogenically). Where an applicator is not utilized, radiation is applied directly to the region of interest after passing through the appropriate optics.

## Claims

1. A method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:

- (a) positioning an element over the skin surface in the said skin region through which optical radiation may be passed; and
- (b) applying optical radiation of a selected wavelength and of a selected fluence through the element to the said skin region for from 2ms to 200 ms.

2. A method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:
  - (a) placing an applicator in contact with the skin surface in the said region; and
  - (b) applying optical radiation of a selected wavelength and of a selected fluence through the applicator to the said skin region, for a predetermined time interval, pressure being applied to the applicator during steps (a) and (b) so as to cause the applicator to deform the skin region thereunder.
3. A method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:
  - (a) utilizing an applicator to form a fold of the skin in the said skin region, the applicator being in contact with the skin surface in the said skin region on two substantially opposite sides of the fold; and
  - (b) applying optical radiation of a selected wavelength and of a selected fluence through the applicator to the said skin region for a predetermined time interval, the optical radiation being applied to the said two substantially opposite sides of the fold.
4. A method according to claim 3 wherein the applicator has a slot formed in the surface thereof in contact with the skin surface, wherein during step (a) at least a portion of the skin region is drawn up into the slot, and wherein during step (b) optical radiation is applied to the skin region from at least two opposite sides of the slot.
5. A method according to claim 2, 3 or 4 wherein the pressure applied to the applicator is greater than blood pressure of a subject from whom hairs are being removed, whereby at least some blood is removed from the skin region.
6. A method according to any of claims 2 to 5 wherein the applicator has a convex surface in contact with the skin surface.
7. A method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:
  - (a) applying optical radiation of a selected wavelength and of a selected fluence to the said skin region for a predetermined time interval; and
  - (b) cooling the skin surface in the said skin region to a selected depth prior to step (a) and during step (a), the said selected fluence and the said predetermined time interval being selected such that there is at most minimal heating of skin in the said skin region to the said selected depth, while causing sufficient heating of at least one of hairs and follicles below the said selected depth to at least damage the hairs and follicles without causing significant damage to tissue surrounding the follicles, whereby at least one of the hairs and follicles is heated and damaged without causing significant damage to the skin surface in the said skin region up to the said selected depth.
8. A method according to claim 7 wherein the selected depth is substantially the entire epidermal layer depth in the region, but does not extend significantly into the dermal layer.
9. A method according to claim 7 or 8 comprising, prior to step (a) placing an applicator in contact with the skin surface in the said skin region, in which step (b) comprises utilizing the applicator to cool the skin surface in the skin region to the said selected depth.
10. A method according to claim 9 wherein step (b) includes the step of (c) cooling at least the surface of the applicator in contact with the skin surface both during step (b) and prior to the performance thereof.
11. A method according to claim 10 wherein step (c) is performed by passing a cooling fluid through the applicator.
12. A method according to claim 9, 10 or 11 wherein step (a) is not performed until the skin surface in the said skin region has been cooled to substantially the said selected depth.
13. A method according to any of claims 2 to 12 wherein said selected time interval is from 2 to 200 ms.
14. A method according to any preceding claim in which the optical radiation is applied to the said skin in the radiation

applying step for up to 100ms.

15. A method according to any preceding claim in which the optical radiation is applied to the said skin in the radiation  
applying step for at least 5ms.

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16. A method according to any preceding claim including before step (a) shaving the hairs in the said skin region.

17. A method according to any of claims 1 to 15 including before step (a) epilating the hairs in the said skin region.

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18. A method according to claim 17 including after the epilating step but before step (a) filling the follicles from which  
the hairs have been epilating with a substance which preferentially absorbs optical radiation at the said selected  
wavelength.

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19. A method according to any preceding claim wherein the said selected fluence and the time interval are such as to  
result in the substantial destruction of the follicles.

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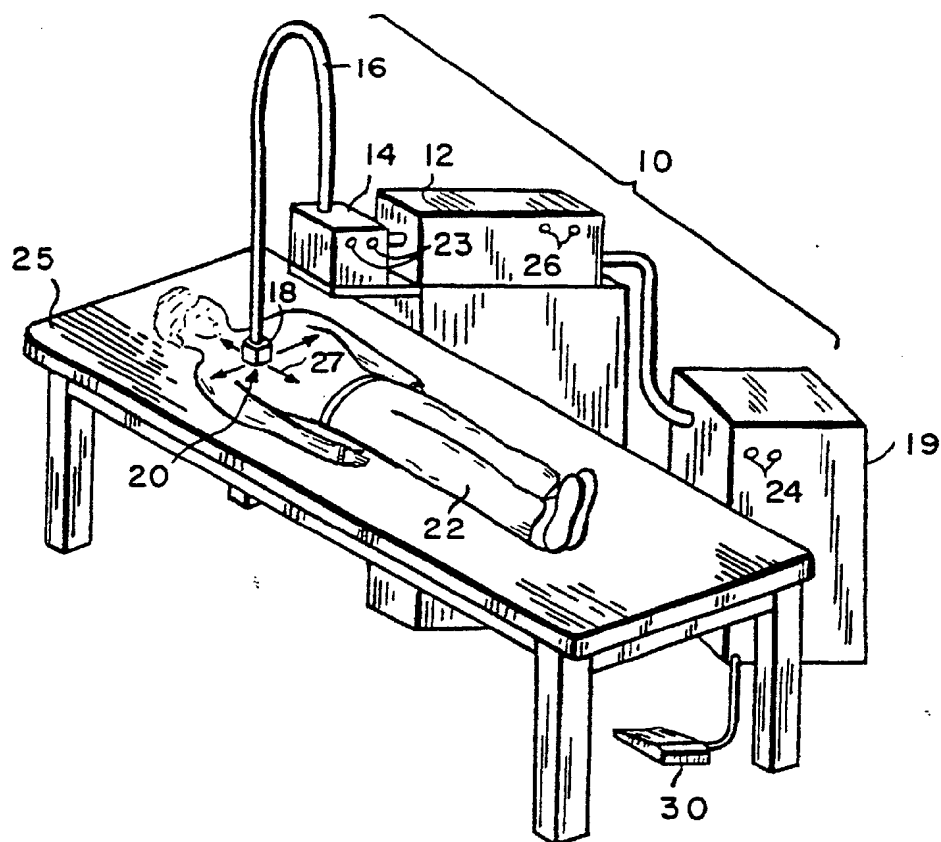


FIG. 1

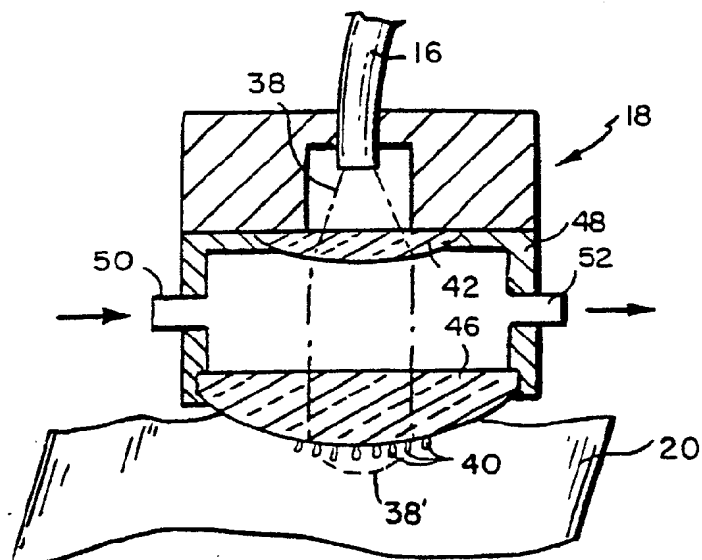


FIG. 2A

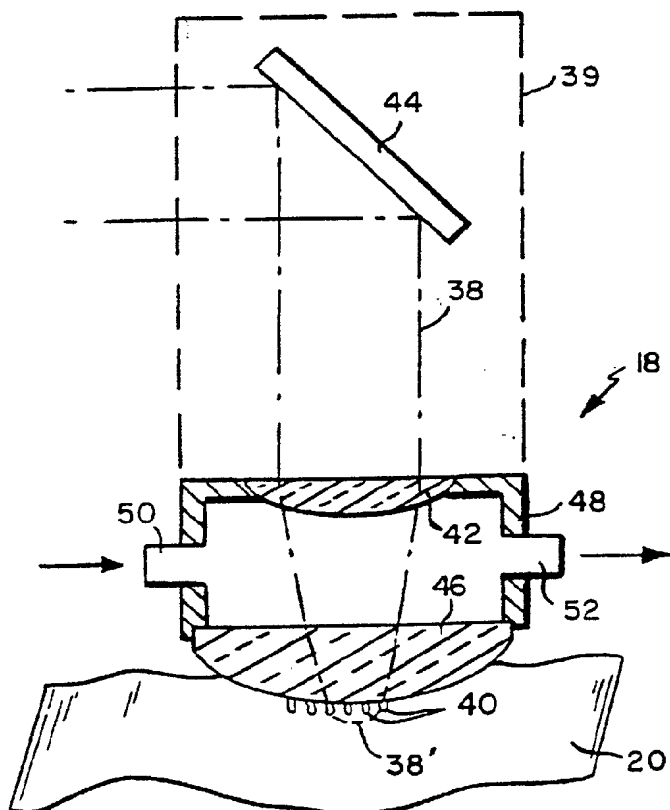


FIG. 2B

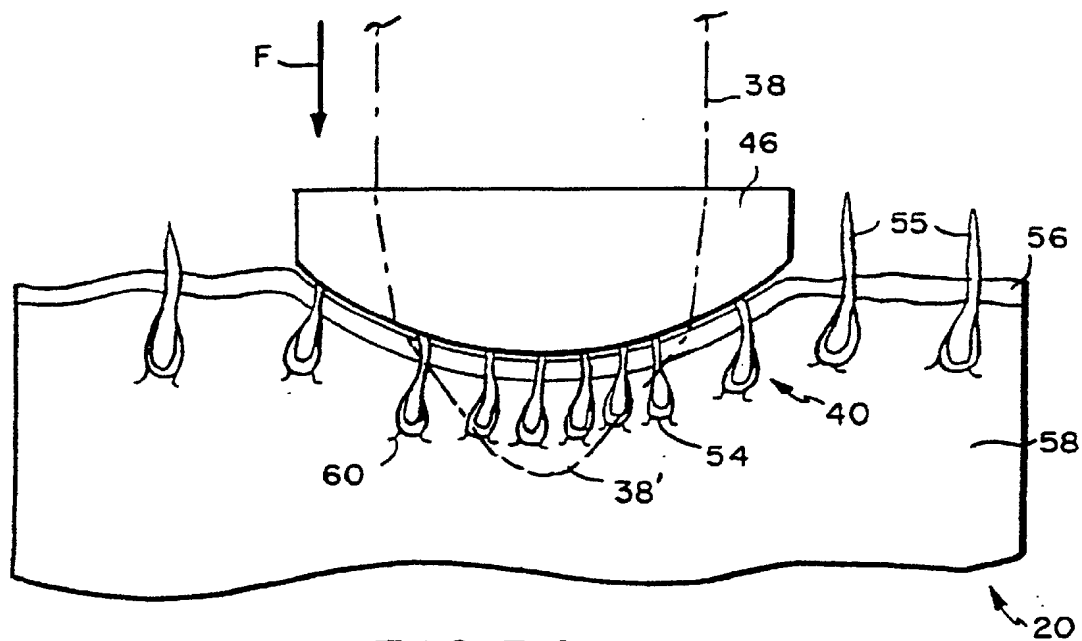


FIG. 3A

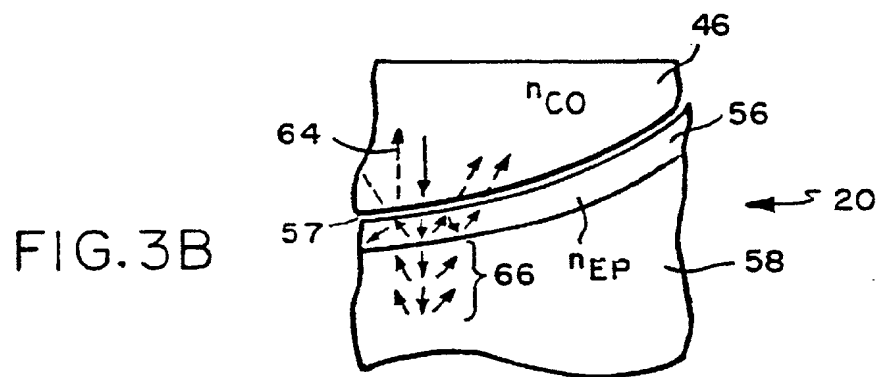


FIG. 3B

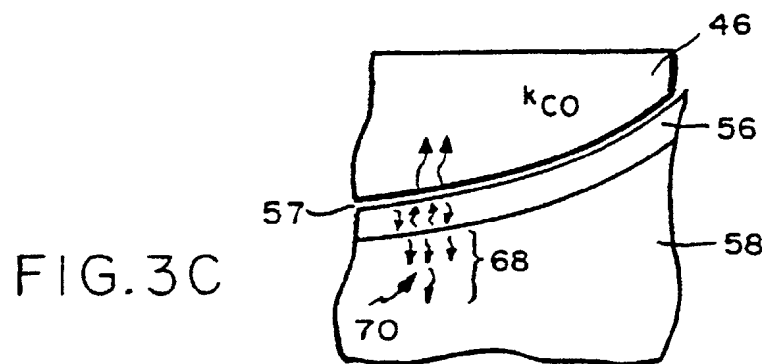


FIG. 3C

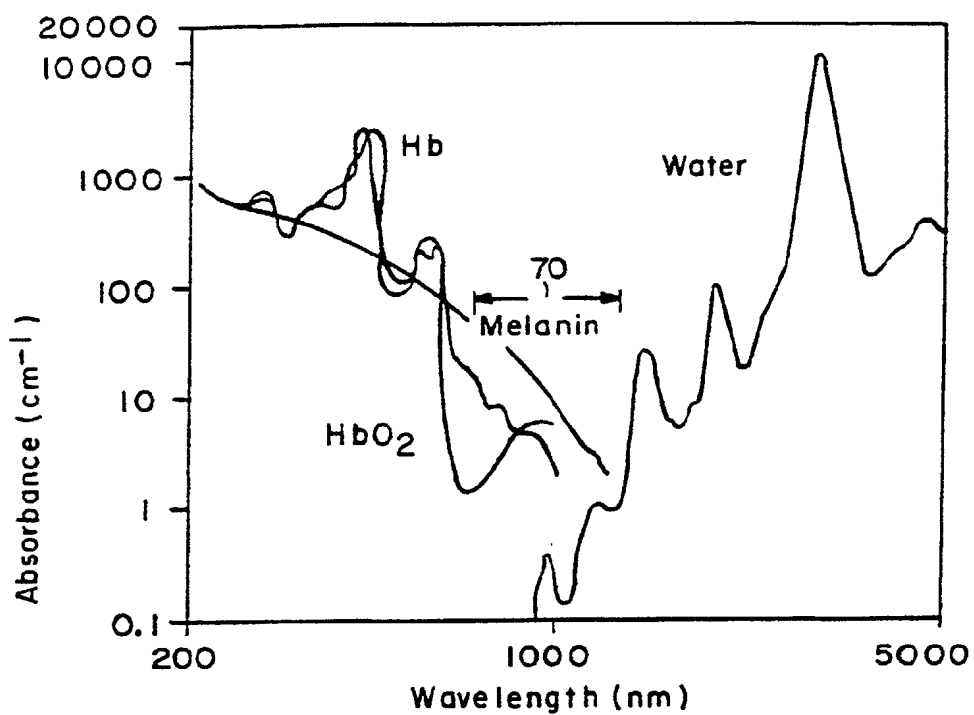


FIG. 4

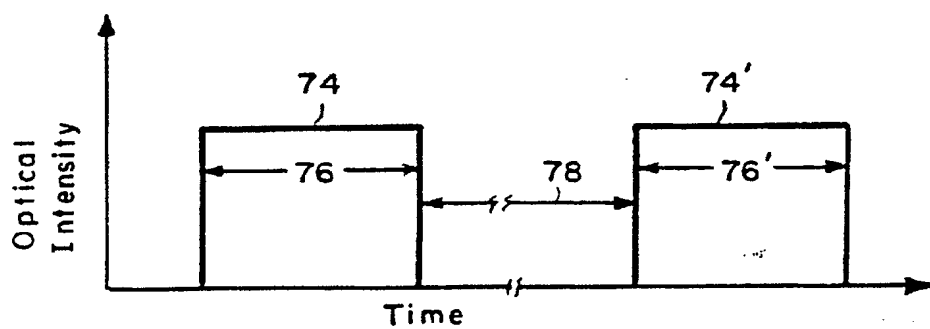


FIG. 5A

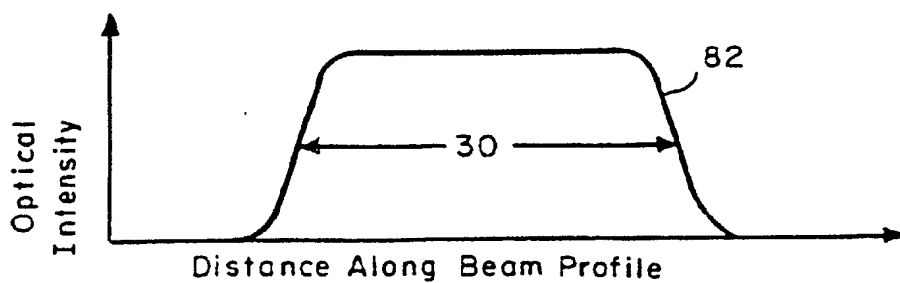


FIG. 5B

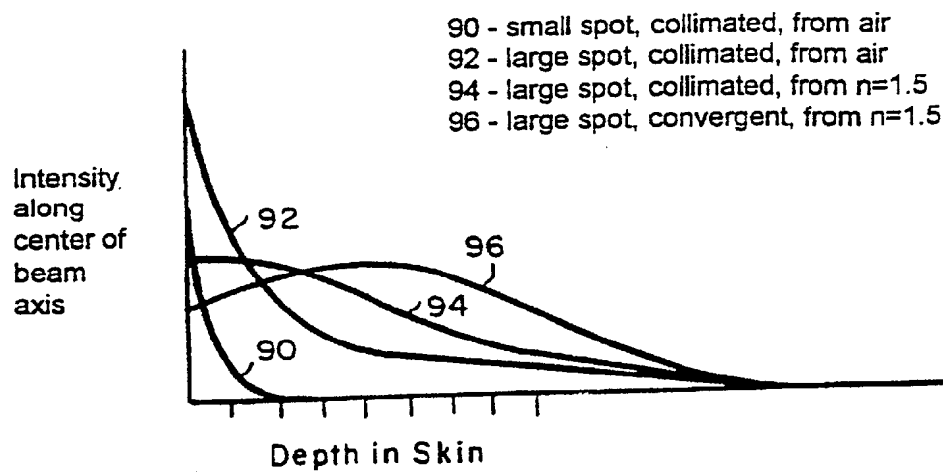


FIG. 6

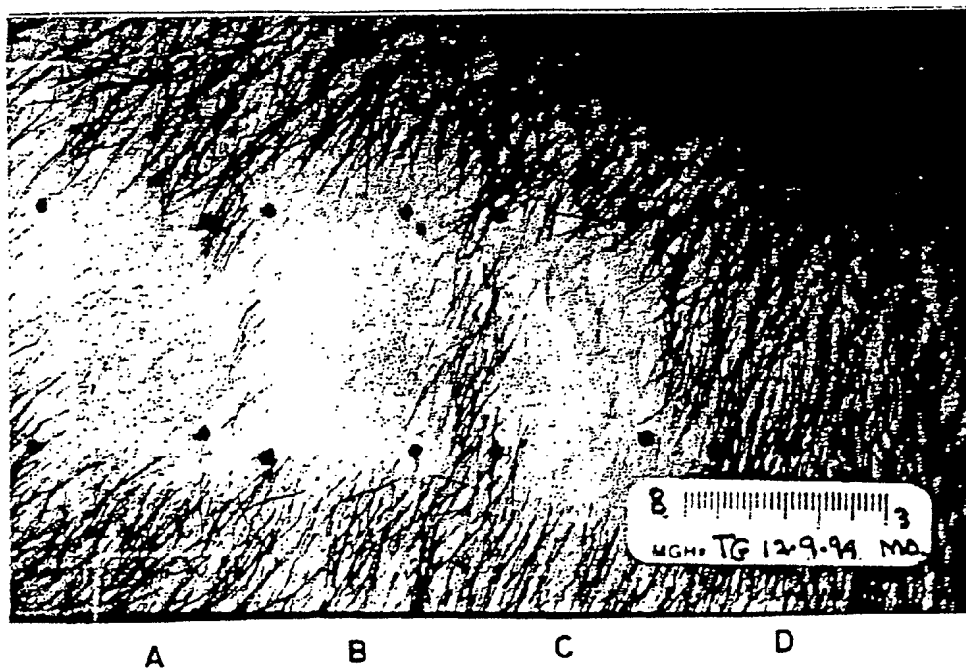
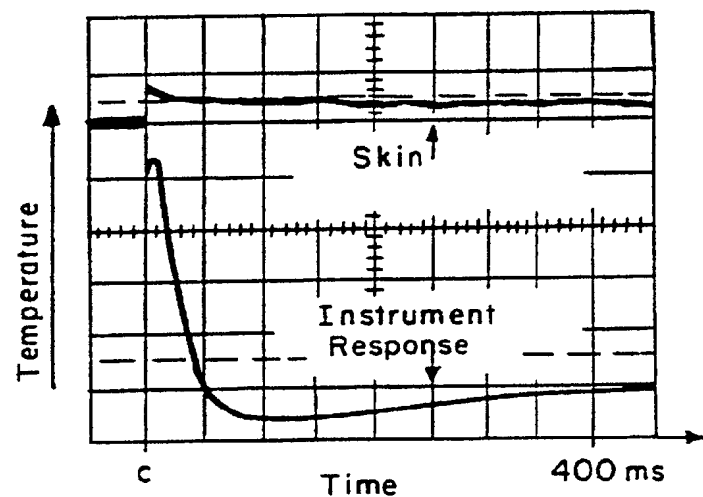
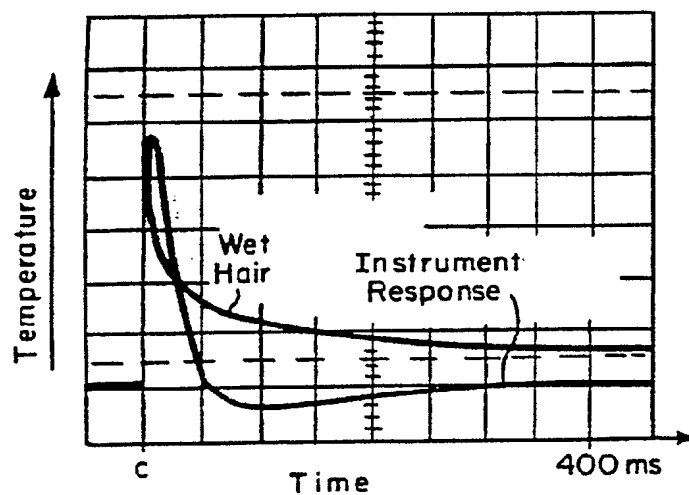
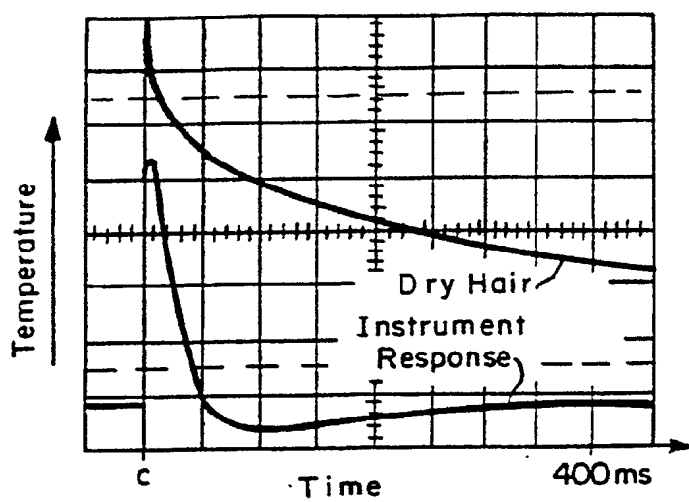


FIG. 7



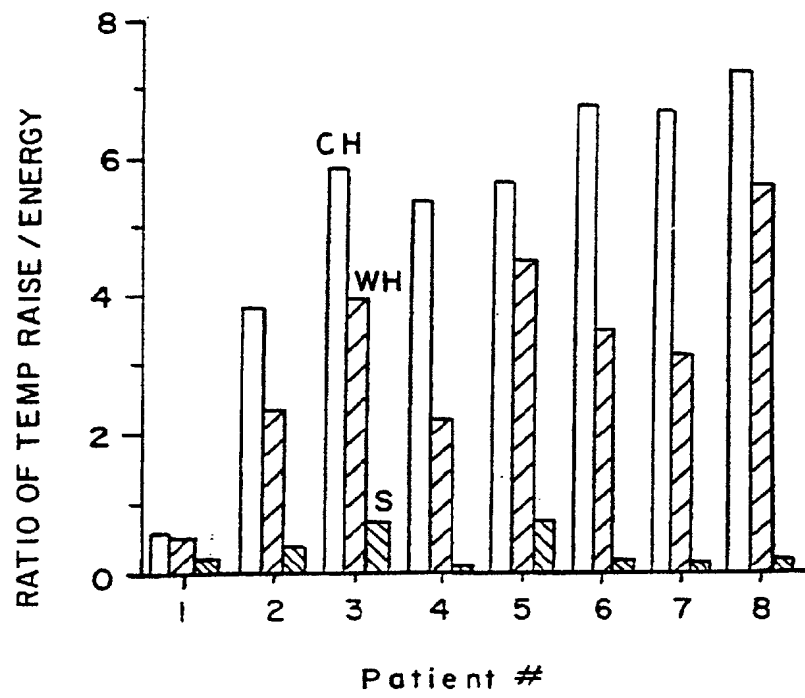


FIG. 9

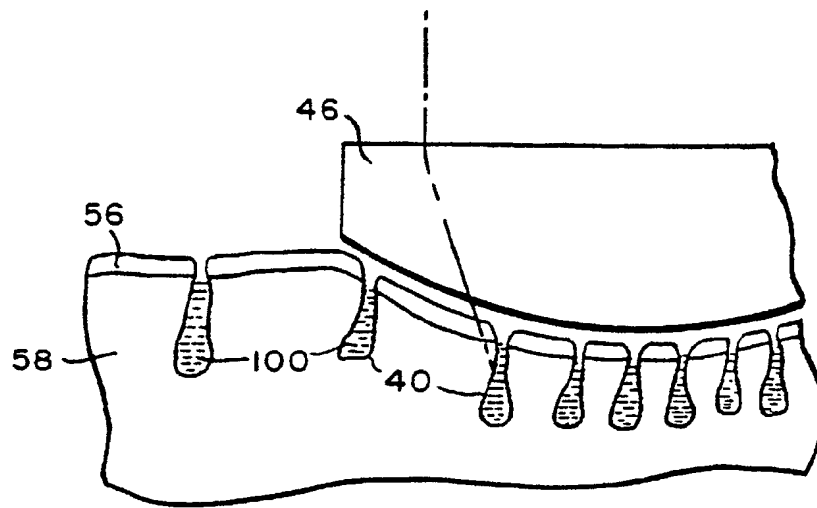


FIG. 10A

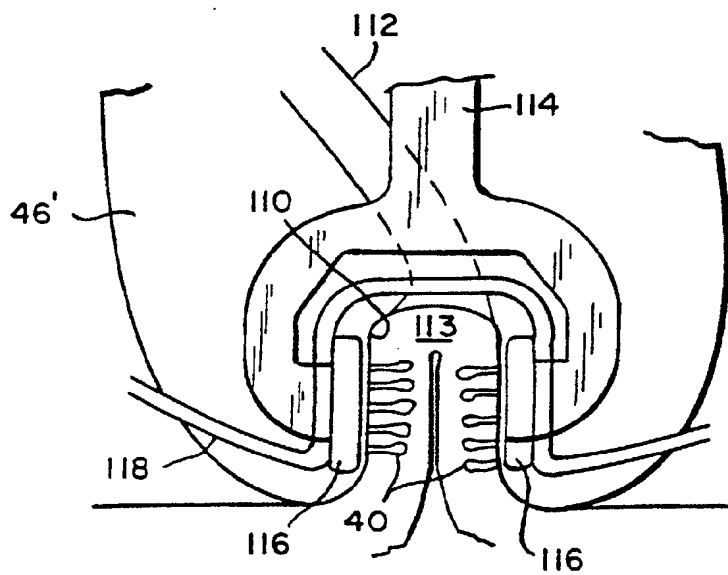


FIG. 10B





European Patent  
Office

# PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

EP 02 07 6295

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	EP 0 142 671 A (BLOCK) 29 May 1985 (1985-05-29) * claim 1 *		A61B18/20
A	US 5 057 104 A (CHESS) 15 October 1991 (1991-10-15) * column 3, line 65 - column 4, line 2 * * column 4, line 51 - line 56 *		
A	GB 2 123 287 A (SUTTON) 1 February 1984 (1984-02-01) * figure 1 *		
A	FR 2 591 902 A (COLLIN) 26 June 1987 (1987-06-26) * page 6, line 2 - line 11 *		
A	WO 93 05920 A (KOZILOWSKI) 1 April 1993 (1993-04-01) * column 6, line 33 - column 7, line 5; figure 2 *		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B A61N A45D B26B A22B A22C
<b>INCOMPLETE SEARCH</b> The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims. Claims searched completely : Claims searched incompletely : 1-19 Claims not searched : Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery			
Place of search		Date of completion of the search	Examiner
THE HAGUE		8 May 2002	Mayer, E
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPC FORM 1503 03 A2 (P04007)

# PARTIAL EUROPEAN SEARCH REPORT

Application Number  
EP 02 07 6295

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A, D	US 5 226 907 A (TANKOVICH) 13 July 1993 (1993-07-13) * claim 1 *		
A	WO 92 16338 A (KELMAN) 1 October 1992 (1992-10-01) * page 6, line 24 - page 7, line 3 *		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)

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EP 02 07 6295

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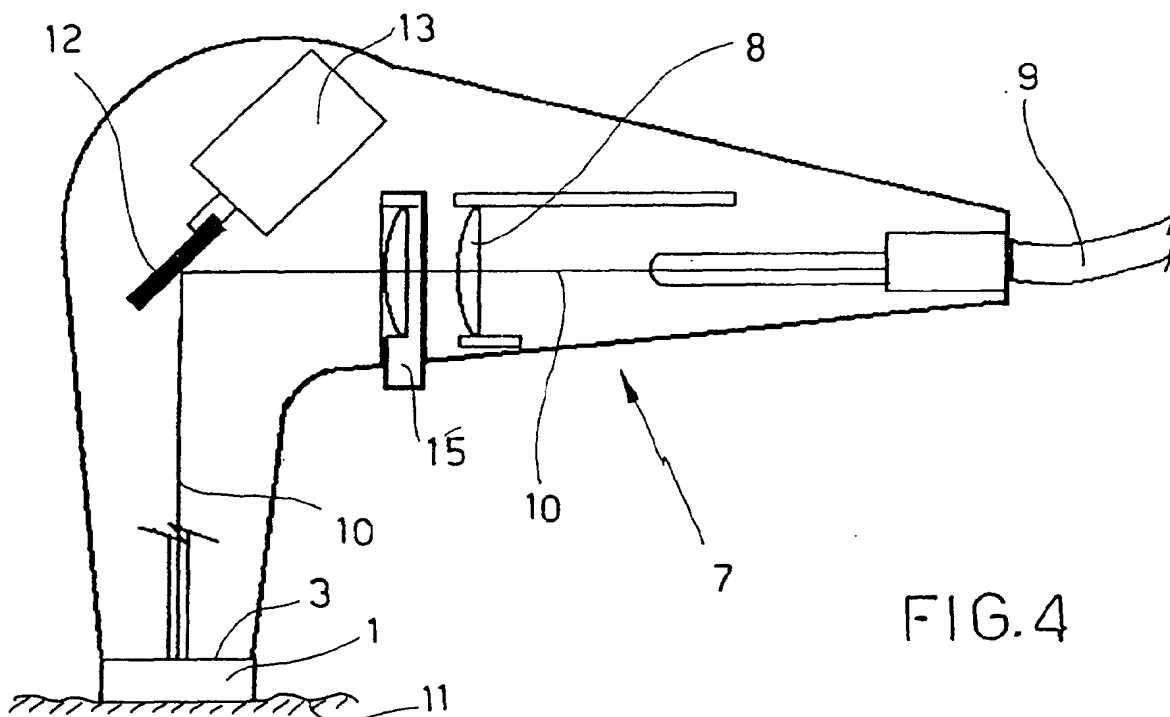
(30) Priority: **29.01.2001 IT MO010008**

(71) Applicant: **Laserwave S.r.l.**  
**41100 Modena (IT)**

(54) **Device for cutaneous treatments using optical radiation**

(57) The invention falls into the field of devices designed to enable cutaneous treatments involving optical radiation. An optical cooling unit (1) is composed of a container with two sides (3) and (4) opposite each other, parallel to each other and spaced out by a cavity (2). The said two sides are composed, for the main part of

their surface, of two optically transparent elements (3a) and (4a). The cavity (2) is designed to enable the continual circulation of a cooling liquid. The optical cooling unit (1) is attached integrally to a device (7) and it is crossed, at a substantially orthogonal angle, by optical radiation (10). Additional optics (15), reciprocally interchangeable, may be inserted in a seating (14).



**FIG. 4**

## Description

**[0001]** The invention relates to a device for cutaneous treatments.

**[0002]** More and more applications are being found for optical radiation, using for example, laser rays, for both operations aimed at eliminating or reducing cutaneous defects of a vascular nature and also those designed to eliminate the presence of hairs in particular areas of the skin.

**[0003]** In the case of the aforesaid defects of a vascular nature, these are usually small superficial lesions or reticules of the epidermal capillaries which are particularly visible and cutaneous marks due to angioma constituted of dilated, tortuous vessel elements which are generally wine red in colour and have an anomalous structure; the said cutaneous defects are mainly located in particularly visible areas of the anatomy, such as the face, neck and lower limbs.

**[0004]** Still with regards to the cutaneous defects, a further example could be the marks which appear with the progression of the ageing process.

**[0005]** Of the other types of cutaneous illness that are treatable with optical radiation, psoriasis (characterised by circumscribed patches with a red background covered with whitish scales) is worth a particular mention.

**[0006]** Also worth mentioning are tattoos, the elimination of which can be performed using cutaneous treatments involving optical radiation. In fact, optical radiation determines the carbonisation of the cells which have absorbed the colourings and the said cells, after their carbonisation, can be eliminated by the blood circulation.

**[0007]** Operations designed to eliminate or limit these defects are of a medical nature which are not disassociated, as explained earlier, from aspects of a cosmetic nature.

**[0008]** Operations designed to remove hair from a particular area of the body are pre-eminently of a cosmetic nature and to understand fully the importance of these treatments, one must simply consider the fact that the presence of hairs in particularly visible areas of the body can lead to serious psychological problems for the person concerned.

**[0009]** The use of optical radiation, in particular laser rays, has led to the realisation of devices capable of dealing successfully with the aforesaid cutaneous defects, both those linked to a defect of a vascular nature and those linked to an excess of hairs.

**[0010]** The commonly known devices all use, substantially, a group of common elements. In fact, there is always a radiating element, a conveyor for the radiation towards one or more condensation lenses of the said radiation and a terminal optical element or unit, commonly designed to be positioned in contact with the cutaneous surface to be treated.

**[0011]** One problem which is common to all the commonly known kinds of devices for cutaneous treatments

which use optical radiation is constituted of the cooling of the cutaneous portion on which the treatment is to be carried out on.

**[0012]** This cooling is important both to produce a localised reduction in the cutaneous temperature and also to produce an always localised absorption of the increase in temperature due to the application of the optical radiation.

**[0013]** The cooling during the treatment has, substantially, both the aim of anaesthetising the part affected by the application of optical radiation and also that of preventing burns and/or denaturing of the skin.

**[0014]** The cooling after the treatment also has a dual purpose: to absorb the accumulation of the heat caused by the application of the optical radiation and to limit the reddening of the skin.

**[0015]** In order to obtain the aforesaid cooling, the commonly known technique offers various solutions among which the first and most simple is the application of cryogenic products in the form of a spray or ice applied directly to the epidermis before the application of the optical radiation.

**[0016]** There are numerous drawbacks to the application of these skin-cooling products: first of all, the application of these products does not coincide with the application of the optical radiation; furthermore, where the cryogenic products in particular are concerned, their extreme volatility must be considered as it causes the cooled part to remain cool for an extremely short space of time only with the consequent cooling effect greatly reduced at the moment of the treatment; furthermore, one should also consider the limits of the depth reached by the cooling applied in this way and also the lack of constancy of the cooling times and, in any case, the reduced ease of use.

**[0017]** The application of the aforesaid cooling products may be performed not only directly onto the portion of the epidermis to undergo the treatment but also on the optical element that will come into contact with the said portion of the epidermis and through which the optical radiation will cross: an example of this can be found in the document US-6,015,404.

**[0018]** A further known solution is constituted of the direct cooling of the said optical element located in direct contact with the epidermis obtained via the conduction principle: in this solution, the said optical element is brought into contact with a metal element kept at a low temperature.

**[0019]** The major drawback of this means of bringing about the cutaneous cooling process is constituted of the mediocre results achieved.

**[0020]** An optical element has been proposed which is cooled by a cooling fluid circulating inside a containing frame of the said optical element. This solution has the drawback that the cooling of the optical element is not a uniform process as the central part of the said element, being further from the said frame, is always at a higher temperature than the peripheral areas nearer the said

frame.

**[0021]** The cooling fluid can be water, water mixed with liquid coolants or even gases such as carbon dioxide, freon and suchlike.

**[0022]** An example of the cooling, with gas, of the optical unit designed to be placed on the epidermis to be treated can be found in the document US-5,344,418.

**[0023]** Lastly, a further proposal for a device equipped with a scanner capable of moving the optical radiation over a larger cutaneous surface than the surface affected by the fixed optic with which the majority of the commonly known devices are equipped; in this way every time the device is placed on the epidermis, the treatment performed covers a larger surface area.

**[0024]** The most advantageous, and therefore the most desirable, characteristic of a device for superficial cutaneous treatments using optical radiation can be resumed as follows: uniformity and certainty of the cooling of both the optical element in contact with the epidermis and the epidermis itself, the amplitude of the surface affected by the treatment, the irrelevance of the shape of the epidemic surface to be treated and the irrelevance of the operator's manual expertise.

**[0025]** Every single one of the commonly known devices has only a few of the most advantageous characteristics mentioned above. None of them seems to have them all simultaneously.

**[0026]** A first aim of this invention is to realise an optical cooling unit which is particularly efficient in the cooling action it performs on the skin and is equipped with an operating surface (through which the optical radiation can pass) capable of guaranteeing an extremely large treatment zone.

**[0027]** A further aim of this invention is to realise a device for superficial cutaneous treatments by means of the use of optical radiation, in particular, laser rays, which has all the most advantageous characteristics listed above at the same time.

**[0028]** A still further aim of this invention is to permit the immediate use of the said device in the performing of cutaneous treatments of a variety of kinds in which a different imprinting of the optical radiation is required on the epidermis, said imprinting being more or less ample depending on the case.

**[0029]** In particular, the device for cutaneous treatments using optical radiation, in particular laser rays, which can be held by hand and comprising a conductor for the aforesaid optical radiation, an optic designed to condense the said radiation, at least one scanner designed to deflect optical radiation, at least one reflective mirror and an optical cooling unit attached integrally to the device, is characterised by the fact that the optical cooling unit is constituted of a container which is substantially parallelepiped in form and is fitted with two openings, identical in size and shape, created on both sides of the said container, the two said sides being opposite each other, parallel to each other and spaced out by a cavity; inside each of the said openings is an opti-

cally transparent element whose surfaces and dimensions are identical to that of the respective opening; the optical cooling unit being attached integrally to the device in such a way as to ensure both optically transparent elements are substantially orthogonal to the direction of the optical radiation; the cavity being designed to enable the circulation of a cooling fluid; and which is equipped with a seating designed to enable the insertion of one of a plurality of additional optics at a time, said additional optics being interchangeable and designed to be positioned inside the device in such a way that they are crossed by optical radiation; the additional optics being designed to vary the focalisation of the said optical radiation on the epidermis.

**[0030]** This and other characteristics will better emerge from the detailed description that follows of a preferred embodiment, provided in the form of a non-limiting example, with reference to the accompanying drawings, in which:

- Figure 1 shows a perspective view of the optical cooling unit;
- Figure 2 shows a view of a lateral longitudinal section of the optical cooling unit;
- Figure 3 shows a perspective view of the unit composed of all the main elements constituting the device;
- Figure 4 shows a lateral transparent view of a possible embodiment of the device;
- Figure 5 shows the same elements as figure 4 with the additional optic seating highlighted;

**[0031]** With reference to the figures, 1 indicates an optical cooling unit with a substantially parallelepiped form, constituting a container.

**[0032]** The said container has two sides 3 and 4 opposite and parallel to each other and spaced out by a cavity 2; each of the said sides has an opening in which a transparent optical element is positioned, respectively 3a and 4a. The surface of each of the said openings occupies almost the totality of the surface of the respective side in which it is located.

**[0033]** The form of the aforesaid opening and consequently of the respective transparent optical elements 3a and 4a is long and their surface is no less than 250mm<sup>2</sup>.

**[0034]** Two orifices 5 and 6 are positioned on the side 3 in position with the portion of the said side which is not occupied by the transparent optical element 3a.

**[0035]** The optical cooling element 1 is attached integrally to a device 7 containing an optic 8 connected to a conductor 9, in the example illustrated constituted of a fibre optic cable, connected to an external optical radiation 10 generator (not illustrated), generating, in particular, a laser ray.

**[0036]** The two transparent optical elements 3a and 4a can be made of either the same material or a different material: in the latter case, for example, the element 3a,

positioned facing the interior of the device 7 can be made of glass while the element 4a, positioned facing the epidermis 11 to be treated can be made of sapphire, quartz, industrial diamond or suchlike.

**[0037]** In front of the optic's 8 radiation 10 output is a mirror 12 inclined in relation to the said radiation. The said mirror is connected to a scanner 13.

**[0038]** On the external body of the device 7 is a seating 14 designed to enable the insertion of an additional optic 15 which is part of a plurality; all the additional optics making up the said plurality are reciprocally interchangeable.

**[0039]** The additional optic 15 is positioned, inside the device 7, in position with the optic's 8 radiation 10 output, between this latter and the mirror 12.

**[0040]** Each of the aforesaid optics 15 has a different focalising power.

**[0041]** The functioning modes of the present invention will now be described with reference to the indications in the figures.

**[0042]** The device 7 is held by the operator and placed on the patient's epidermis 11 in position with the cutaneous zone to be treated. The contact between the said device and the said epidermis is performed by means of the transparent optical element 4a, preferably made of a material such as sapphire or industrial diamond or a similar material with a greater level of thermal conductivity than common glass.

**[0043]** The cooling fluid which flows continuously within the cavity 2, entering the said cavity through the orifice 5 and leaving it via the orifice 6, keeps both the transparent optical elements 3a and 4a, and consequently also the portion of epidermis 11 in contact with the element 4a, at a low temperature.

**[0044]** The said cooling action is exerted before, during and after the cutaneous treatment by means of the optical radiation 10, in particular a laser ray. The said treatment, thanks to the ample surface of the transparent optical elements 3a and 4a, allows for the use of optical radiation 10, which, thanks to the scanner 13, is deflected along the aforesaid elements.

**[0045]** The pressure applied by the operator onto the device 7 is transmitted onto the skin in position with the contact between the said skin and the transparent optical element 4a; said pressure leading to the dilation of the pores and increasing tautness of the skin, facilitates the transmission of the cooling effect to the said skin with the consequent increased depth of the penetration of the said cooling effect through the thickness of the skin.

**[0046]** The aforesaid pressure exerted by the transparent optical element 4a on the skin also leads to a reduction in the distance between the optical cooling unit 1 and the capillaries or piliferous bulbs or cells to be treated.

**[0047]** Thanks to the uniform cooling of the element 4a and thanks also to the long form of both the transparent optical elements 3a and 4a, the application of the

cutaneous treatment is also possible in anatomical zones that are neither flat nor regular in shape and, so, cannot be reached by the commonly known types of device.

**[0048]** Depending on the dimensions of the imprinting of the radiation 10 on the epidermis 11, the said dimensions being a variable which depends on the cutaneous operation required, one inserts the additional optic 15 with the focalisation power required into the device 7, making use of the relevant seating 14.

**[0049]** The said additional optic is part of a plurality and all the optics belong to the said plurality, while having different focalisation powers, are reciprocally interchangeable.

**[0050]** It should also be noted that the presence of the scanner 13, deflecting the optical radiation 10, allows the operator to treat a larger zone of skin with a constant energy distribution, without moving the device 7. In this way localised accumulations of energy are prevented and consequently so too is cutaneous damage.

**[0051]** A first advantage offered by the device in question in this invention lies in the fact that the cooling system of the optical cooling unit 1 provides certainty and uniformity in the cooling action exerted on the cutaneous zone to be treated.

**[0052]** A further advantage lies in the fact that, thanks to the form and the dimensions of the transparent optical elements 3a and 4a, the device 7 can be used to treat any cutaneous zone, regardless of the shape of the said zone and regardless of the operator's manual ability.

**[0053]** A still further advantage offered by this invention lies in the size of the cutaneous surface that can be treated, the said surface being 250mm<sup>2</sup>.

**[0054]** A still further advantage is that all the advantageous characteristics just mentioned are incorporated in a single device.

**[0055]** A further advantage lies in the possibility of obtaining, by means of the said device, different focalisations of the optical radiation on the epidermis by inserting additional optics into the said device, said optics being reciprocally interchangeable, thus obtaining greater flexibility of use with regards to the device in question in this invention.

**[0056]** In the description, specific reference has been made to the existence, inside the device in question in this invention, of a single scanner 13 and a single mirror 12, but it is clear that the number of these components could also be greater without reducing the said device's functioning efficiency.

## Claims

1. A device (7) for cutaneous treatments using optical radiation (10), in particular a laser ray, of a handheld kind and comprising, at least, one conductor (9) for the aforesaid optical radiation, at least one scanner (13) designed to deflect the optical radiation (10),



at least one mirror (12) to reflect the said radiation, and an optical cooling unit (1) attached integrally to the device (7), **characterised by** the fact that the optical cooling unit (1) is constituted of a container which is substantially parallelepiped in form and has two openings, both identical in terms of dimensions and form, located on the two sides (3) and (4) of the said container, the said two sides being opposite each other and parallel and spaced out by a cavity (2); in each part of the said openings is placed a transparent optical element, respectively (3a) and (4a), with dimensions which are substantially identical to those of the respective opening; the optical cooling unit (1) being attached to the device (7) in such a way that both transparent optical elements (3a) and (4a) are crossed by the optical radiation (10) reflected by at least one mirror (12); the cavity (2) being designed to enable the circulation of a cooling fluid; and which is fitted with a seating (14) designed for the insertion of a single additional optic (15) at a time, said additional optic being part of a plurality of optics which are reciprocally interchangeable and are designed to be positioned inside the device (7) in such a way that the said optics are crossed by the optical radiation (10); the additional optics (15) being designed to vary the focalisation of the said optical radiation on the epidermis (11).

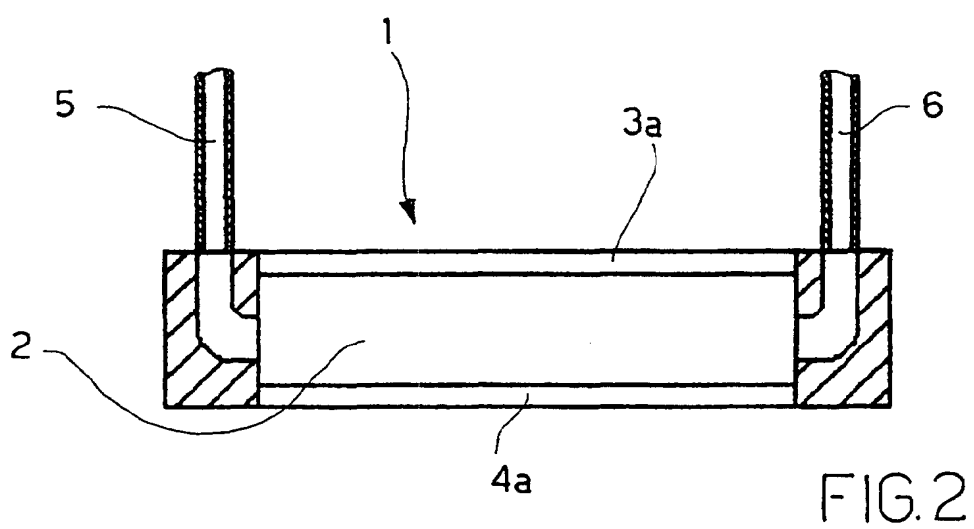
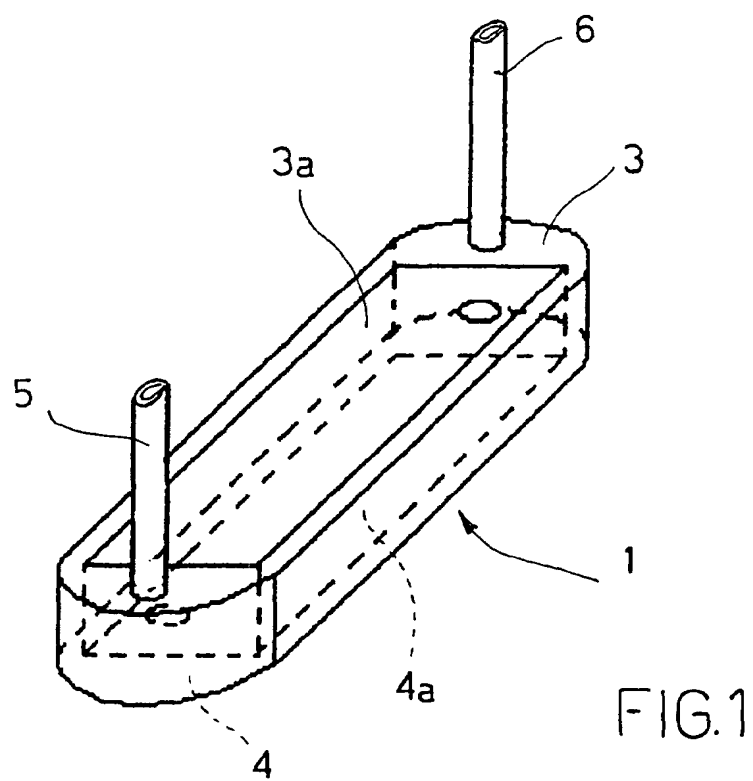
2. A device according to claim 1, **characterised by** the fact that the attachment between the optical cooling unit (1) and the device (7) is such that the transparent optical element (3a) is positioned facing the interior of the said device and the transparent optical element (4a) is positioned facing the exterior of the said device; the external surface of the element (4a) being designed to be placed on the portion of epidermis (11) to be treated.

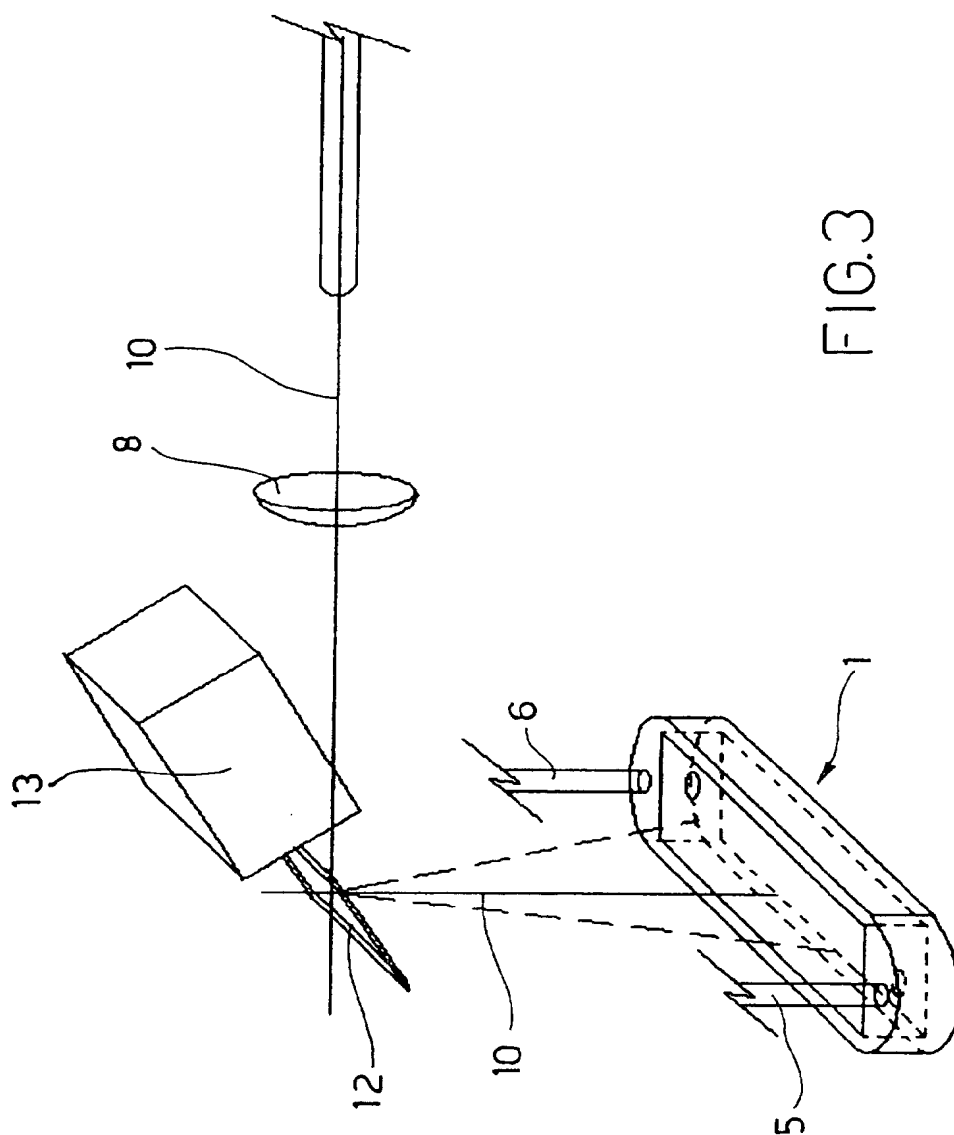
3. A device according to claims 1 and 2, **characterised by** the fact that the transparent optical elements (3a) and (4a) both have a surface of at least 250mm<sup>2</sup> which occupies almost the totality of the surface of the respective side (3) and (4); the said dimensions being designed to permit, contemporaneously, both the deflection of the optical radiation (10) and the contact with the external surface of the transparent optical element (4a) even on portions of epidermis which are not flat and/or are irregular.

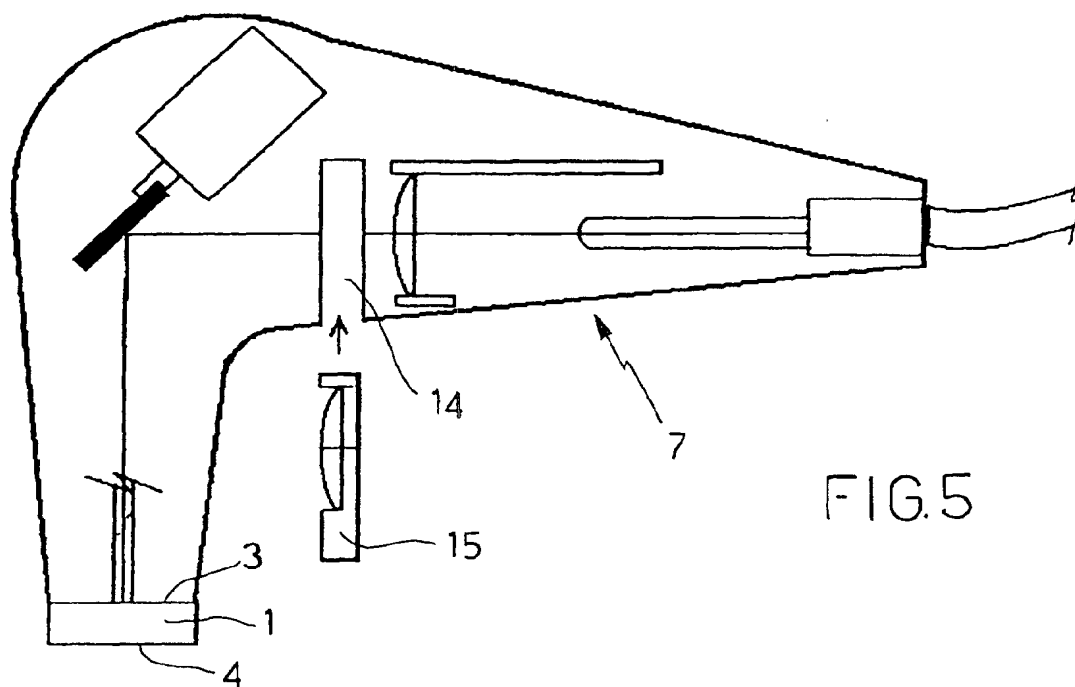
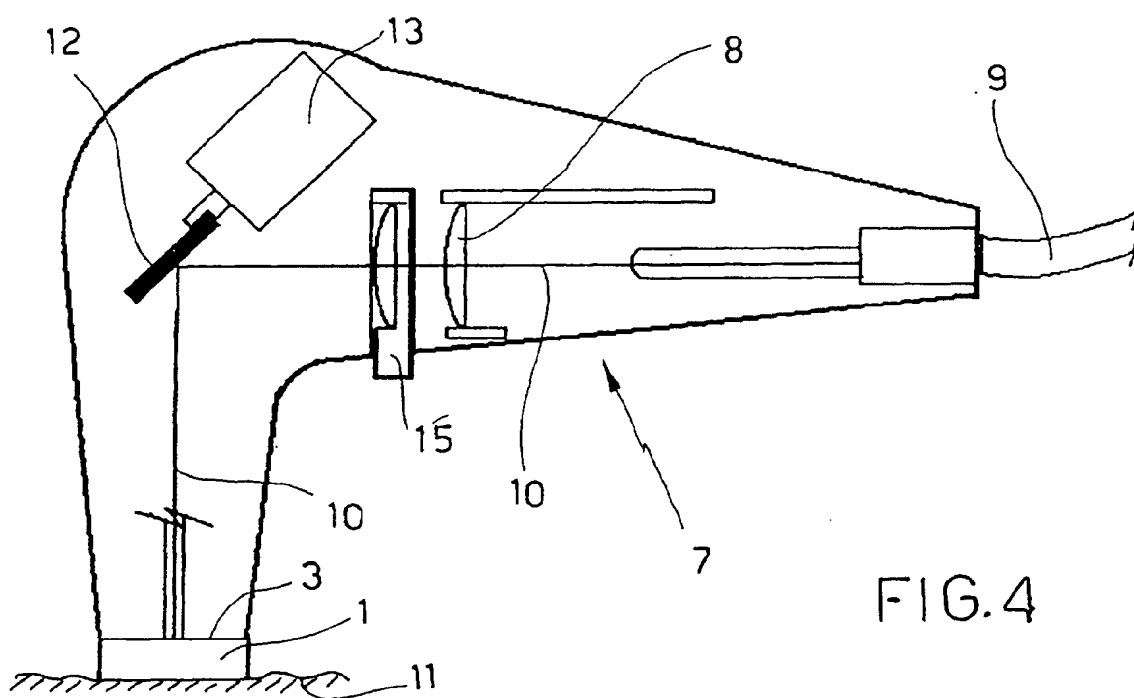
4. A device according to claims 1, 2 and 3, **characterised by** the fact that the two transparent optical elements (3a) and (4a) can be made of either the same material or different materials: in the case of the different materials, for example, the element (3a), positioned facing the interior of the device (7) can be made of glass, while the element (4a) positioned facing the epidermis (11) to be treated can

be made of sapphire, quartz, industrial diamond or suchlike; the choice of the said latter materials being based on the degree of thermal conductivity required.

5. A device according to claim 1 **characterised by** the fact that the optical cooling unit (1) is kept watertight and has two orifices (5) and (6), for, respectively, the inlet and output of the cooling fluid contained within the cavity (2); the said orifices being connected to a circulation and cooling circuit for the said fluid.
6. A device according to claims 1 and 5, **characterised by** the fact that the temperature of the cooling fluid is maintained within a range from -10°C and +5°C.
7. A device according to claims 1, 5 and 6, **characterised by** the fact that the cooling fluid can be constituted solely of water, of a mixture of water and glycol or suchlike, or even of cryogenic gas.
8. A device according to claims 1, 5, 6 and 7, **characterised by** the fact that the flow of the cooling fluid inside the optical cooling unit (1) is continuous for the entire time the device (7) is in use.
9. A device according to claim 1, **characterised by** the fact that each of the additional optics (15) has its own distinctive focalising power.









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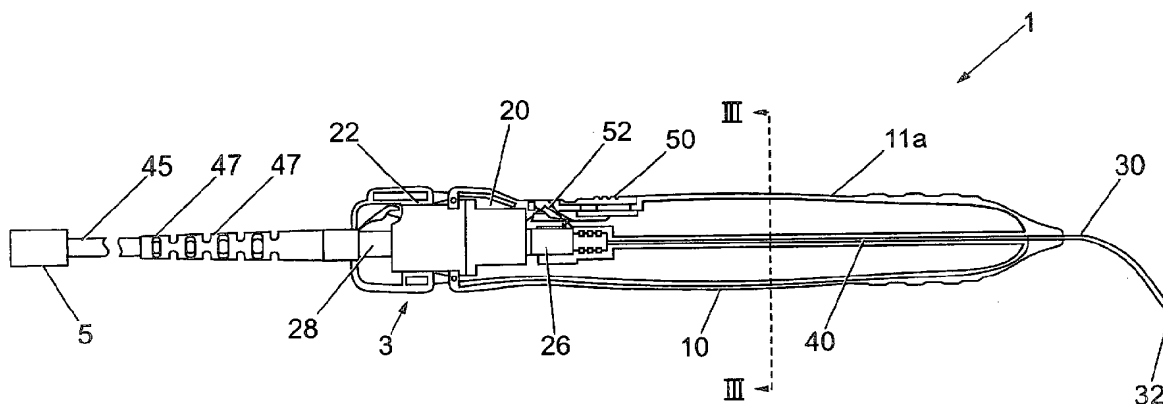
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(54) **Hand apparatus for light delivery**

(57) A hand apparatus comprises a housing, an optical connector (20) provided in the housing adapted for connection to a light source (3), and an elongate sleeve

(30). The sleeve (30) has a light emitter (32) at one end and an optical carrier (40) extending from the optical connector (20) to the light emitter (32).



*Fig. 1*

## Description

**[0001]** This invention relates to a hand apparatus for delivery of a beam of light, for example a collimated laser beam, to a point of application.

In particular the invention relates to a hand apparatus for delivery of a laser beam to a point of application on a tooth in a patient's mouth.

**[0002]** Hand pieces are used in medicine, dentistry and other forms of treatment to apply light locally to an area being treated. The light may be generated at a base unit and transmitted along a cable to a fixed hand piece. Alternatively the base unit may include a power source, with electrical power transmitted along a cable to a hand piece to generate the light at the hand piece itself. The flexible cable connection allows the operator of the hand piece to move the hand piece easily to the required point of application.

**[0003]** The known hand pieces suffer from the disadvantage that they must be sterilised between uses. The hand pieces contain precise optical components, so that they cannot be sterilised in the way that mechanical apparatus can. One solution is to provide a disposable sleeve around the hand piece. The sleeve is discarded and replaced between uses of the hand piece. However this solution suffers from the disadvantage that the sleeve cannot be totally effective in eliminating contamination from one use to the next.

**[0004]** It is an object of the present invention to provide a hand apparatus for delivery of a beam of light, for example a collimated laser beam, to a point of application, wherein the apparatus is inexpensive to manufacture and simple to connect to a light source, so that the hand apparatus can be used as a single use apparatus, eliminating the requirement to sterilise the apparatus for reuse.

**[0005]** According to a first aspect of the present invention there is provided a hand apparatus comprising a housing, an optical connector provided in the housing adapted for connection to a light source, an elongate sleeve having a light emitter at one end, and an optical carrier extending from the optical connector to the light emitter.

**[0006]** Preferably the optical connector is a male or female optical connector adapted for connection of optical telecommunication fibres. Preferably the optical connector includes a resiliently biased optical coupler to ensure contact between the optical coupler of the connector and the light source to which it is to be connected.

**[0007]** The apparatus may include a safety means which prevents light being transmitted if the optical connector is disconnected from the light source. Preferably the apparatus includes a switch adapted to operate a detent member which allows disconnection of the connector from the light source upon operation of the switch.

**[0008]** The light emitter may be an isotip emitter of the sort described in United States Patent No. 5,073,402.

**[0009]** Preferably the housing is of moulded plastic. The housing may be provided in two snap-fit parts. Preferably the housing is an elongate housing and includes means for retaining the optical carrier within the housing. Preferably the retaining means is adapted to permit longitudinal movement of the optical carrier relative to the channel during connection of the connector to a light source.

**[0010]** Preferably the retaining means includes an internal channel extending from the connector to the sleeve. Preferably the optical carrier extends along the channel.

**[0011]** Preferably the optical carrier includes at least one optical fibre.

**[0012]** The apparatus may also comprise a fluid delivery system. Preferably the fluid delivery system includes a reservoir, a fluid outlet adjacent the light emitter, and a conduit connecting the reservoir and the fluid outlet. The conduit may allow the passage of fluid from the fluid reservoir to the outlet adjacent the light emitter via the housing and the sleeve.

**[0013]** Preferably the sleeve is a resiliently flexible sleeve. The sleeve may be plastically deformable such that an operator can deform the sleeve to a required shape. Preferably the sleeve is adapted to permit longitudinal movement of the optical carrier relative to the sleeve upon deformation or flexing of the sleeve. Preferably the sleeve is of stainless steel.

**[0014]** According to a second aspect of the present invention there is provided a light delivery system comprising a light source and a hand apparatus, the light source including a first optical connector and the hand apparatus including a second optical connector, wherein the first and second optical connectors are male and female optical connectors adapted for connection of optical telecommunication fibres.

**[0015]** Preferably the first optical connector includes a first optical coupler and the second optical connector includes a second resiliently biased optical coupler to ensure contact between the first and second optical couplers when the first and second optical connectors are connected.

**[0016]** The light delivery system may include a safety means which prevents light being transmitted if the optical connector is disconnected from the light source. The safety means may be provided on the light source or the hand apparatus. Preferably the light delivery system includes a switch adapted to operate a detent member which allows disconnection of the first and second optical connectors upon operation of the switch.

**[0017]** Preferably the hand apparatus further comprises a housing, an elongate sleeve having a light emitter at one end, and an optical carrier extending from the second optical connector to the light emitter.

**[0018]** The light delivery system may also comprise a fluid delivery system. Preferably the fluid delivery system includes a reservoir, a fluid outlet adjacent the light emitter, and a conduit connecting the reservoir and the

fluid outlet. The conduit may allow the passage of fluid from the fluid reservoir to the outlet adjacent the light emitter via the housing and the sleeve.

**[0019]** An embodiment of the invention will now be described, by way of example only, with reference to the accompanying figures, where:

Fig. 1 is a cross sectional view of a hand apparatus according to a first embodiment of the invention;

Fig. 2 is an isometric cross sectional view of the hand apparatus of Fig. 1;

Fig. 3 is a partial cross sectional view at III-III of the hand apparatus of Fig. 1;

Fig. 4 is an isometric view of the hand apparatus of Fig. 1; and

Fig. 5 is a partial enlarged view of the switch of the hand apparatus of Fig. 1.

**[0020]** Referring to Figs. 1 and 2 there is shown a hand apparatus 1 according to an embodiment of the present invention, comprising a housing 10, a second optical connector 20 provided in the housing 10 and adapted for connection to a light source 3, an elongate sleeve 30 having a light emitter 32 at one end, and an optical carrier 40 extending from the optical connector 20 to the light emitter 32.

**[0021]** The second optical connector 20 is connected to a first optical connector 22 provided in a connector housing 24. Both connectors 20, 22 are typically standard optical telecommunication connectors such as those manufactured by Stratos Lightwave. Standard connectors allow accurate optical coupling of the fibre ends within a low tolerance (typically 1 micron).

**[0022]** The first optical connector 22 is typically a female connector and the second optical connector 20 is typically a male connector. This ensures that no optical carriers 40 are exposed while the first optical connector 22 is connected to the light source 3 but not connected to the second optical connector 20.

**[0023]** The optical carrier 40 comprises a number of optical fibres arranged in a bundle and generally surrounded by a sheath (not shown). The light source 3 includes a light generator 5 and an optical cable 45 comprising a number of optical fibres within a shielding connecting the light generator 5 to the first optical connector 22 in the connector housing 24. The cable 45 may include ribs or thickened portions 47 adjacent to the hand apparatus for increased flexural strength, flexural stiffness and fatigue life.

**[0024]** A switch 50 is provided on the housing 10. The switch may be seen most clearly in Fig. 5. The switch 50 is connected through a slot 58 to a cam member 54. When the switch 50 is operated in the direction of arrow 60, the cam member 54 is driven forward in the direction

of arrow 60. This forward travel of the cam member 54 causes the hinged latch control member 56 to move downwardly and engage with a latch member 52 which also moves downwardly and causes the first optical connector 22 to decouple from the second optical connector 20. An abutment member 62 is also connected to the switch 50 and after a predetermined amount of forward movement, during which the optical connector 22 is decoupled as described above, abuts the first optical connector 22 causing the first and second optical connectors to separate. This separation provides a visible signal to the operator that the hand piece 1 can be removed from the light source 3. It is to be understood that the switch mechanism illustrated in Fig. 5 is only one possible switch mechanism and may be replaced by any suitable hand operated coupling and decoupling system.

**[0025]** A suitable safety means (not shown) may also be provided such that light may only be transmitted from the first optical coupler 22 if the first optical coupler 22 is connected to the second optical coupler 20. The safety means may be an electronic switch which is broken when the hand apparatus 1 is disconnected from the light source 3, causing an electronic signal to be sent along wires (not shown) in the cable 45 to turn off the light generator 5.

**[0026]** The housing 10 comprises two components 11a, 11b joined to each other using snap-fit connection or other suitable means. The housing 10 is typically manufactured from moulded plastic. The housing is substantially cylindrical in shape.

**[0027]** Fig. 3 shows one component 11a of the housing in cross section (at III-III in Fig. 1) and also the optical carrier 40. The housing, at this axial location, includes a web portion 14 extending from the outer circumference towards the centre. The web portion 14 divides into two split web portions 15, which together with the two split web portions 15 of the other component 11a define a channel 16 in which the optical carrier 40 is supported in a way which allows transverse movement within the channel.

**[0028]** The ends 18 of the outer circumferential portion of the component 11a are profiled to allow snap-fit connection with correspondingly shaped ends 18 of the other component 11b. When the two components 11a, 11b of the housing 10 are joined, the split web portions 15 of the two components of the housing 10 form a channel which houses the optical carrier 40 and extends along the axis of the housing 10 from the second optical connector 20 to the sleeve 30.

**[0029]** Fig. 4 shows the hand apparatus with the two components 11a, 11b of the housing 10 joined. At one region of the exterior surface of the housing 10 there is provided a grip portion 12 having an embossed surface. This region is typically located near the sleeve end of the housing.

**[0030]** Referring also to Figs. 1 and 2, the sleeve 30 is fixed at one end within the housing 10. At the other

end of the sleeve 30 is located the light emitter 32. The light emitter may be an isotip optical emitter of the sort described in United States Patent No. 5,073,402.

**[0031]** The internal diameter of the sleeve 30 is substantially greater than the external diameter of the optical carrier 40. The sleeve 30 is typically made of stainless steel or other suitable metal. This allows the sleeve 30 to be permanently bent into a position desirable to the user. Because the optical carrier 40 is free to move longitudinally relative to the sleeve 30, bending the sleeve 30 causes no damage to the optical carrier 40.

**[0032]** The optical carrier 40 is constrained where it is joined to the second optical connector 20 and is fixed at the light emitter 32 but is otherwise unconstrained, and is free to move laterally within the channel 16 and within the sleeve 30. The optical carrier 40 is rigidly secured to the second coupler 26, which is mounted within the second connector 20 in a resiliently biased manner, in order to ensure a firm connection between the second coupler 26 and the first coupler 28, which is fixedly mounted in the first connector 22. When the first 22 and second 20 optical connectors are connected, the second coupler 26 moves longitudinally relative to the second connector 20 as it is brought into contact and pressed against the first coupler 28. It is therefore important that the housing accommodates relative longitudinal movement of the optical carrier 40, which is fixed to the second coupler 26, and the housing 10, which is fixed to the second connector 20. This relative longitudinal movement is accommodated by the fact that the channel 16 in which the optical carrier 40 sits is much wider than the carrier itself. Hence the carrier 40 is free to adopt a serpentine profile in order to accommodate the longitudinal movement of the end attached to the second coupler 16. The dimensions of the channel 16 typically allow up to 2 mm relative longitudinal movement.

**[0033]** The hand apparatus 1 as described is inexpensive to produce. It is intended that the hand apparatus 1 be a disposable unit. The light source 3, including the first optical connector 22 and the connector housing 24 and the associated cabling 45 are intended to be more permanent. The hand apparatus 1 can readily be disconnected from the light source 3 by simple separation of the first and second optical connectors 20, 22 and replaced by another hand apparatus. If required different types of hand apparatus 1 having different lengths of housing 10 and/or different lengths and/or shapes of sleeve 30 may also be provided.

**[0034]** The hand apparatus 1 may also be used to provide other functions, particularly dental functions. For instance, a fluid conduit (not shown) may also be provided within the housing 10 that supplies fluid, such as mouthrinse, to a spout (not shown) located adjacent to the light emitter 32.

**[0035]** Modifications and variations to the invention described above are possible without departing from the scope of the invention.

## Claims

### 1. A hand apparatus comprising:

a housing;  
an optical connector provided in the housing adapted for connection to a light source;  
an elongate sleeve having a light emitter at one end, and an optical carrier extending from the optical connector to the light emitter.

### 2. A hand apparatus according to Claim 1, wherein the optical connector is a male or female optical connector adapted for connection to optical telecommunication fibres.

### 3. A hand apparatus according to Claim 1 or Claim 2, wherein the optical connector includes a resiliently biased optical coupler to ensure contact between the optical coupler of the connector and the light source to which it is to be connected.

### 4. A hand apparatus according to any preceding claim, including safety means adapted to prevent light being transmitted if the optical connector is disconnected from the light source.

### 5. A hand apparatus according to any preceding claim, wherein the apparatus includes a switch adapted to operate a detent member which allows disconnection of the connector from the light source upon operation of the switch.

### 6. A hand apparatus according to any previous claim, including retaining means for retaining the optical carrier within the housing, the retaining means being adapted to permit longitudinal movement of the optical carrier relative to the channel during connection of the connector to a light source.

### 7. A hand apparatus according to Claim 6, wherein the retaining means comprises an internal channel extending from the connector to the sleeve, the optical carrier extending along the channel.

### 8. A hand apparatus according to any preceding claim, including a fluid delivery system comprising:

a reservoir;  
a fluid outlet adjacent the light emitter; and  
a conduit connecting the reservoir and the fluid outlet, the conduit allowing the passage of fluid from the fluid reservoir to the outlet adjacent the light emitter via the housing.

### 9. A hand apparatus according to any preceding claim, wherein the sleeve is adapted to permit longitudinal movement of the optical carrier relative to



the sleeve upon deformation or flexing of the sleeve.

10. A hand apparatus according to any preceding claim, wherein the sleeve is a resiliently flexible sleeve. 5

11. A hand apparatus according to any of Claims 1 to 9, wherein the sleeve is plastically deformable. 10

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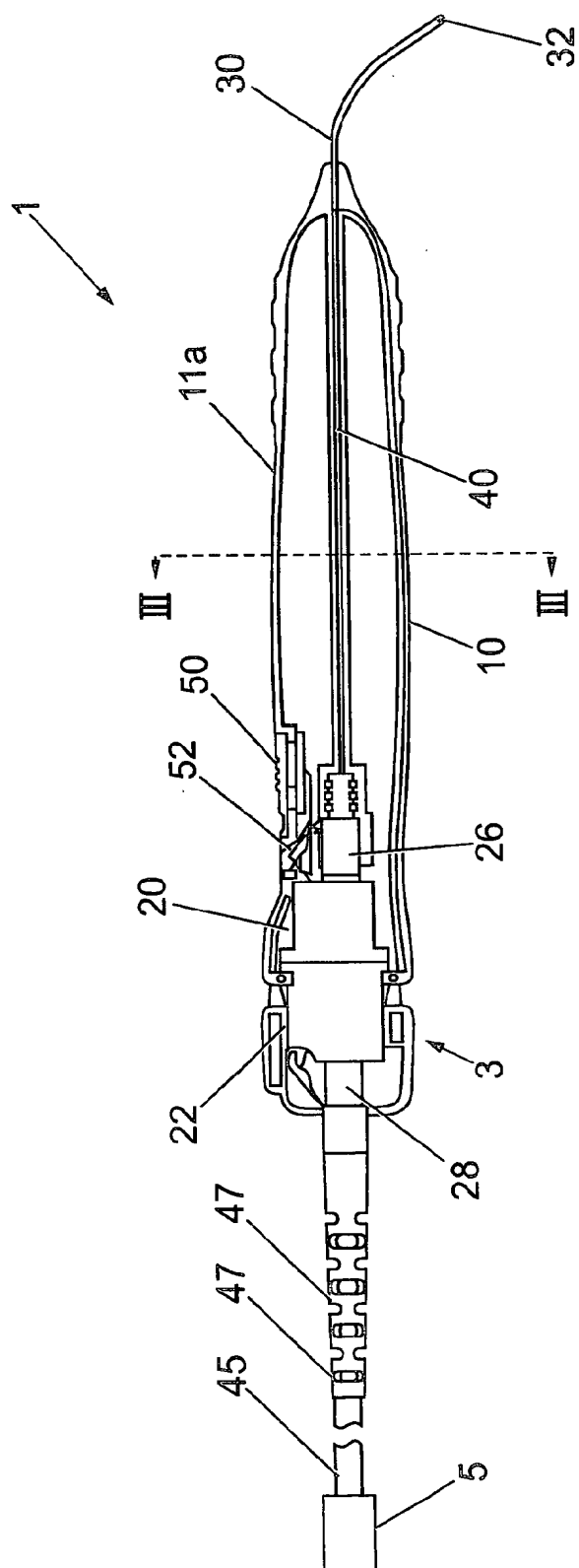


Fig. 1

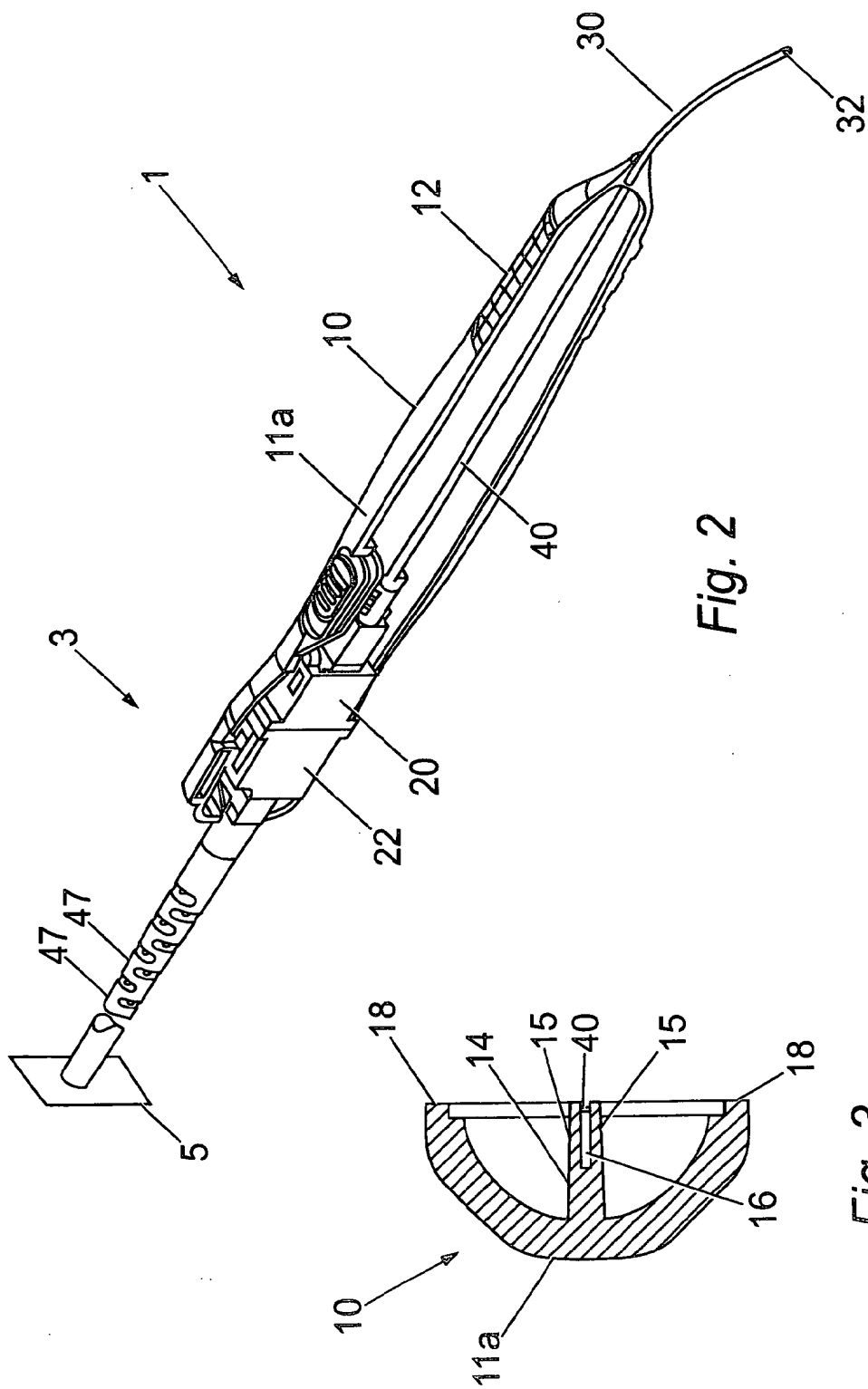
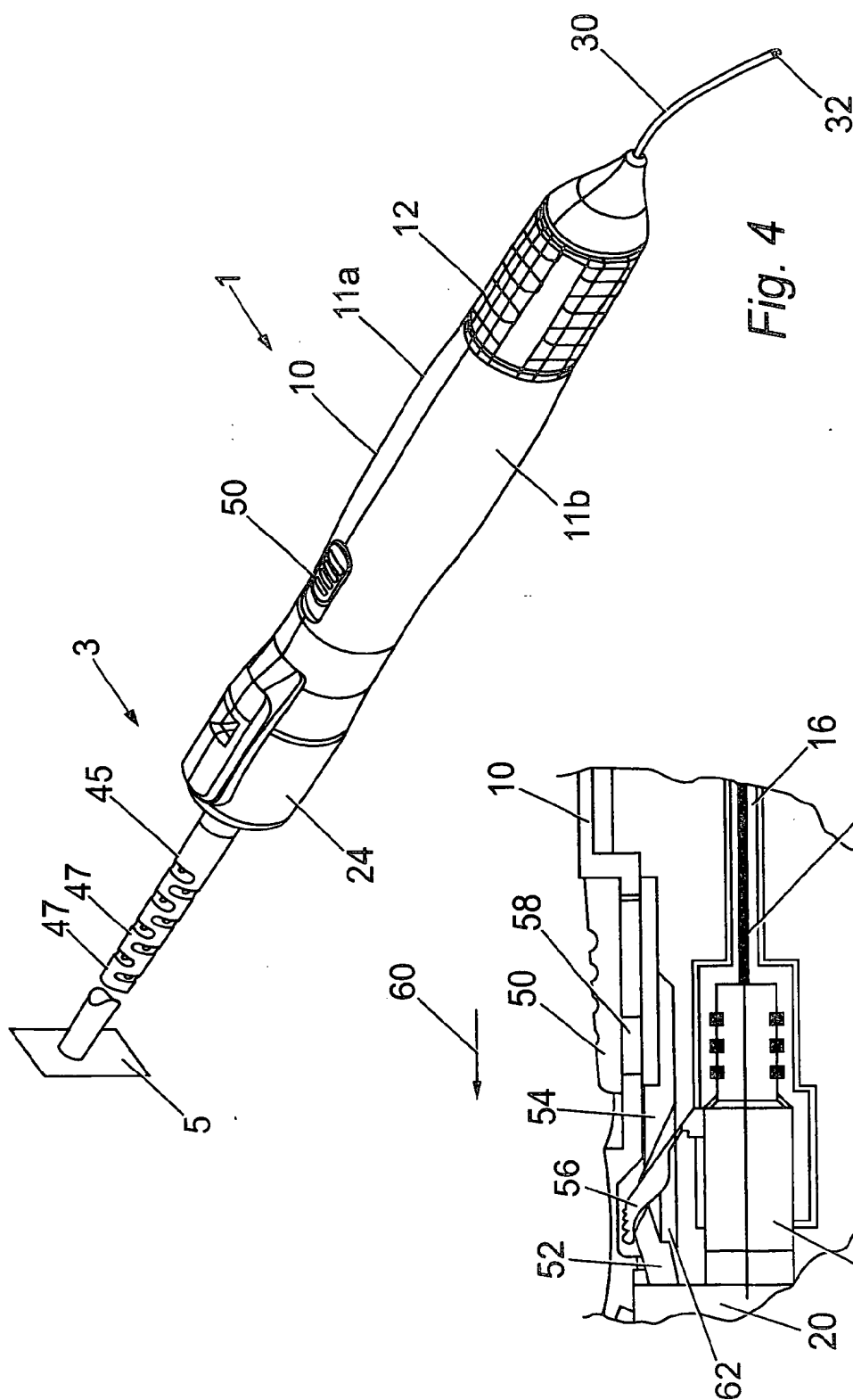


Fig. 2

Fig. 3





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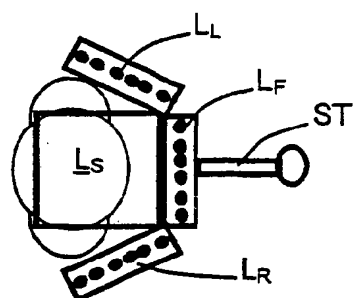
Remarks:

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(54) **Therapeutic light source and method**

(57) A therapeutic light source comprises rigid arrays of LED's ( $L_F$ ,  $L_L$ ,  $L_R$ ) movably connected together, and cooled by forced air convection. The output intensity of the arrays is at least 10mW/cm<sup>2</sup> with a spatial intensity fluctuation of 10% or less in the treatment field. The emission spectra of the LED's may be substantially limited to the range 400 to 430 nm, or 590 to 640 nm. The light source may be used for cosmetic treatment, such as skin rejuvenation, wrinkle removal and/or biostimulation.

Fig. 20a



## Description

**[0001]** The present invention relates to a non-coherent light source for use in therapy such as photodynamic therapy (PDT), particularly using light emitting diodes (LED's).

**[0002]** Photodynamic therapy involves the administration of a photosensitising drug to an affected area, and its subsequent irradiation with light - see for example 'The Physics of Photodynamic Therapy' by B C Wilson and M S Patterson, Physics in Medicine & Biology 31 (1986) April No. 4, London GB.

**[0003]** The document GB 2,212,010 discloses a therapeutic light source which uses an array of discrete LED's as an alternative to lasers or laser diodes. The output of the LED's is focussed so as to provide the necessary intensity.

**[0004]** The document WO 94/15666 discloses a therapeutic light source specifically for PDT, with an integrated array of LED's mounted on the distal end of a hand piece. The LED's are overdriven to give the necessary intensity, and cooled by the flow of water around a closed loop passing along the hand piece. The document US 5728090 discloses a somewhat similar device with various different types of head containing integrated LED matrices. These devices require complicated liquid cooling circuits which would add to the cost of the device and add to the bulk of the hand piece, which is disadvantageous for invasive use.

**[0005]** The document US 5728090 mentions that the wavelength of the LED's is between 300 nm and 1300 nm and is selected based upon the particular photosensitive dye used during PDT. However, the wavelengths of LED's capable of providing the necessary intensity for PDT cannot freely be chosen within that range.

**[0006]** According to one aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a non-planar array of light-emitting diodes conforming with the shape of an external area to be treated or diagnosed.

**[0007]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.

**[0008]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.

**[0009]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.

**[0010]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.

**[0011]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on the surface thereof an array of discrete light-emitting diodes.

**[0012]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an air-cooled array of LED's, the air being vented in the vicinity of the array. In one embodiment, the array is mounted at the distal end of a hand piece suitable for invasive therapy.

**[0013]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's coupled to a light guide for delivering the light to the area to be treated. Preferably, the LED's are directly coupled without intervening optical devices.

**[0014]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with emission spectra substantially limited to the range 550 to 660 nm, and preferably to one of the ranges 590 to 640 nm, 560 to 644 nm, 650 to 660 nm, and 550 to 570 nm.

**[0015]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm, 470 nm, 505 nm or 525 nm.

**[0016]** According to another aspect of the invention, there is provided a light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on a flexible backing, the array including light-emitting diodes of a first type having a first emission spectrum and light-emitting diodes of a second type having a second emission spectrum different from the first emission spectrum. Preferably, said light-emitting diodes of the first type are independently switchable from said light-emitting diodes of the first type. The first emission spectrum may be substantially in the range 370 to 450 nm, or 400 to 430 nm. The second emission spectrum may be substantially in the range 620 to 700 nm. The light source may be used in the treatment of a pre-cancerous condition, such as an actinic keratosis or a non-melanoma. The non-melanoma may be a basal cell or squamous cell carcinoma.

**[0017]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a non-planar array of discrete light-emitting diodes mounted on a head portion for attachment to the head of a patient such that light is emitted onto the face of the patient.

**[0018]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a first rigid array of light-emitting diodes, a second rigid array of light emitting diodes movably connected to an edge of the first array and a third rigid array of light-emitting diodes movably connected to another edge of the first array. The light source may further include a fourth array of light-emitting diodes movably to a further edge of the first array. The light source may be arranged for treatment of the face and/or scalp.

**[0019]** According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a support for supporting the patient and an array of light-emitting diodes mounted on the curved inner surface of a rigid cover arranged to cover at least part of the length of a patient when supported by the support. The support may include a further array of light-emitting diodes. The further array may comprise a plurality of sections which are independently switchable. The further array may be planar.

**[0020]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing. The aperture and housing may be dimensioned to allow one or both elbows of the patient to be inserted into the housing.

**[0021]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising a plurality of independently switchable co-planar arrays of light-emitting diodes.

**[0022]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising a housing in the form of a trapezoid prism open at the base and having an upper inner surface carrying an array of light-emitting diodes. At least one of the inner side faces may be reflective. At least one of the inner side faces may carry a further array of light-emitting diodes.

**[0023]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on a surface thereof an array of discrete light-emitting diodes. The surface may be substantially cylindrical or substantially spherical.

**[0024]** According to another aspect of the present invention, there is provided a therapeutic light source, comprising an array of light-emitting diodes arranged so that light from the light-emitting diodes is incident directly on the treatment field with an intensity of at least approximately 10 mW/cm<sup>2</sup>, and means for cooling the diodes by forced air convection.

**[0025]** According to another aspect of the present invention, there is provided a therapeutic light source, comprising an array of discrete light-emitting diodes arranged to give an output intensity of at least approximately 10 mW/cm<sup>2</sup>, and means for cooling the diodes by forced air convection.

**[0026]** In either of the two aspects immediately above, the light-emitting diodes may have a spatial intensity fluctuation of approximately 10% or less in the treatment field.

**[0027]** In either of the two aspects immediately above, the diodes may be mounted at the distal end of a passage for carrying the air from the proximal to the distal end. There may be a fan mounted at the proximal end of the passage. The distal end may be dimensioned so as to be locatable proximate a cervix such that light from the diode array is incident on the cervix. The distal end may be concave so as to fit over the cervix.

**[0028]** In any of the above aspects, the diodes may be thermally coupled to one or more heatsinks.

**[0029]** According to another aspect of the present invention, there is provided a therapeutic light source, comprising an array of discrete light emitting diodes coupled to a tapered light guide arranged to concentrate light emitted by the light-emitting diodes. There may be a parallel-sided light guide coupled to the tapered light guide so that the light emitted by the light-emitting diodes is concentrated into the parallel-sided light guide.

**[0030]** According to another aspect of the present invention, there is provided a therapeutic light source, comprising an integrated array of light emitting diodes coupled directly to a parallel-sided light guide. The diodes may be thermally coupled to thermoelectric cooling means. The parallel-sided light guide may comprise one or more optical fibres and/or liquid light guides.

**[0031]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of light emitting diodes having emission wavelengths substantially within the range 550 to 660 nm.

**[0032]** In one embodiment, the emission wavelengths are within the range 590 to 640 nm, and the diodes may be of aluminium indium gallium phosphide/gallium phosphide die material.

**[0033]** In another embodiment, the emission wavelengths are substantially within the range 560 to 644 nm and the diodes may be of aluminium indium gallium phosphide/gallium arsenic die material.

**[0034]** In another embodiment, the emission wavelengths are substantially within the range 650 to 660 nm and the diodes may be of aluminium gallium arsenic die material.

**[0035]** In another embodiment, the emission wavelengths are substantially within the range 550 to 570 nm and the diodes are of gallium phosphide die material.

**[0036]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 470 nm, 505 nm or 525 nm. The diodes may be of indium gallium nitride die material.

**[0037]** According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm. The diodes may be of gallium nitride/silicon die material.

**[0038]** In any of the above aspects, the LED's may include a first set of LED's and a second set of LED's having different emission spectra from said first set.

**[0039]** The array may be mounted on a flexible circuit board.

**[0040]** According to another aspect of the present invention, there is provided a therapeutic light source, comprising an LED array including a first set of LED's and an independently switchable second set of LED's having different emission spectra from said first set.

**[0041]** According to another aspect of the present invention, there is provided a light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second, spatially distinct set of LED's independently switchable from said first set.

**[0042]** The light source of any of the above aspects may be used for cosmetic treatment of a patient. The treatment may be photodynamic, and may be for portwine stain removal, or hair restoration or removal.

**[0043]** The light source of any of the above aspects may be used for skin rejuvenation, wrinkle removal or biostimulation.

**[0044]** The light source of any of the above aspects may be used for medical treatment of a patient. The treatment may be photodynamic, and may be for one or more of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism.

**[0045]** Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a diagram of a parallel-series matrix of discrete LED's used in first and second embodiments of the present invention;

Figure 2 is perspective diagram of the first embodiment;

Figure 3 is a cross section of part of the first embodiment;

Figure 4 is a graph showing the variation of intensity in a cross-section of the output of the first embodiment;

Figure 5 is a cross-sectional diagram of a second embodiment;

Figure 6 is a cross-sectional diagram of a third embodiment;

Figure 7 is a cross-sectional diagram of a fourth embodiment;

Figure 8 is a cross-sectional diagram of a fifth embodiment;

Figure 9 is a graph showing the absorption spectrum of PpIX and the emission spectra of two examples of LED's suitable for use with the embodiments;

Figures 10a and 10b are side and front views respectively of an LED array in a sixth embodiment for treatment of the face;

Figures 11a, 11b and 11c are a cross-section in the plane of the patient's arm, a top view and a vertical cross-section transverse to the patient's arm of an LED array in a seventh embodiment for treatment of the elbows of a patient;

Figure 12 is a side view of an LED array in an eighth embodiment used for treatment of the foot or feet;

Figure 13 is a side view of an LED array in a ninth embodiment used for treatment of the lower leg;

Figures 14 and 15 show arrangements of an LED array in tenth and eleventh embodiments for treatment of re-



spectively the face and a section of a patient lying on a bed;

Figures 16a and 16b show respectively front and side views of a set of similar LED arrays in an twelfth embodiment for treatment of one side of a patient;

Figures 17a and 17b show respectively front and side views of an LED array in a thirteenth embodiment for treatment of a section of one side of a patient;

Figures 18a and 18b are respectively side and end views of a set of similar LED arrays in a fourteenth embodiment, for treatment of one side of a patient lying down;

Figures 19a and 19b are respectively side and end views of an LED array in a fifteenth embodiment for treatment of a section of a patient lying down;

Figures 20a and 20b are top and side views respectively of an arrangement of LED arrays in a sixteenth embodiment for treatment of the face and/or scalp;

Figure 21 shows a similar arrangement to that of Figures 20a and 20b, in a seventeenth embodiment for treatment of the face and/or scalp of a patient lying down;

Figures 22a, 22b and 22c show respectively a side view, a transverse cross-section and a longitudinal cross-section of an LED array arranged within a sleeve in an eighteenth embodiment, for treatment of the hand, forearm and/or elbow;

Figures 23a, 23b and 23c show respectively two different shapes of flexible LED array, and a flexible array applied as a patch onto the skin of a patient, in an nineteenth embodiment;

Figure 24 shows an LED array arranged on the side of a cylindrical intraluminal probe in a twentieth embodiment;

Figure 25 shows an LED array arranged on the surface of a spherical intraluminal probe in a twenty-first embodiment; and

Figure 26 shows a more specific example of the flexible LED array in the nineteenth embodiment.

**[0046]** In a therapeutic light source in the first embodiment, as illustrated in Figures 1 to 5, light is emitted from a parallel-series matrix of LED's L connected through a current-limiting resistor R to a source of a voltage +V. The LED matrix is mounted on a heatsink array H parallel to and spaced apart from a fan array F by support rods R. Air is blown by the fan array F onto the back of the heatsink array H.

**[0047]** As shown in more detail in Figure 3, the heatsink array H comprises a plurality of individual heatsinks h mounted on the ends of the legs of the LED's, which pass through a support plate P. Each leg is soldered to an adjacent leg of another of the LED's in the same column. The support plate P is perforated to allow air to flow more freely around the heatsinks h and the LED's L.

**[0048]** The LED's L are arranged so as to produce a substantially uniform illumination of  $\pm 10\%$  or less across a treatment field by selecting the beam divergence and spacing of the LED's L so that their individual beams overlap without causing substantial peaks or troughs in intensity. In the example shown in Figure 4, uniformity of  $\pm 6\%$  is achieved. In this embodiment, no optical system is needed between the LED's and the patient; instead, the light is emitted directly from the LED's onto the patient. As the light is not concentrated by any optical system, the LED's have individual power outputs of at least 5 mW and preferably at least 10 mW, to give the necessary fluence rates in the treatment field of at least 30 mW/cm<sup>2</sup> in the red region of the spectrum and at least 10 mW/cm<sup>2</sup> in the blue region.

**[0049]** In one specific example, a 15 cm diameter array of 288 'Super flux' LED's was used to produce a total light output of 8 W at 45 mW/cm<sup>2</sup> in the treatment field. The LED's were driven at a higher current load than their specification while being cooled by forced air convection from the fans F. In the specific example, the current was limited to 90 mA per column of diodes, but may be increased to 120 mA or more if increased light output is needed. The number of diodes in series, in each column, is selected so that the total forward operating voltage is as close as possible to, but less than, the power supply output voltage, in this case 48 V. This arrangement avoids wasteful in-circuit heating and maximizes the operating efficiency of the electrical system.

**[0050]** A method of treatment for oncological and non-oncological skin diseases such as cases of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis

fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism, using the first embodiment, will now be described. A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected area of the skin of the patient, or administered intravenously or orally. In another method of application for large areas, the patient may be immersed in a bath of solution. The affected area may then be covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is then uncovered and exposed to light from the lamp according to the first embodiment for a period of 15 to 30 minutes. The treatment may then be repeated as necessary, for a total of 1 to 3 treatments. This method is particularly suitable for the treatment of patients with very large lesions or multiple lesions extending over a large area.

**[0051]** In a method of treatment using the device of the first embodiment, the LED array is positioned approximately parallel to an external affected area of a patient to be treated, with a separation sufficient to achieve the uniform illumination as shown in Figure 4, for example 2 to 5 cm. The device may also be used for cosmetic or partially cosmetic treatment with a photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

**[0052]** The lamp may also be used for fluorescence detection (photodiagnosis).

**[0053]** The first embodiment may be modified in a second embodiment, as shown in Figure 5, by the addition of a frusto-conical waveguide W, for example of acrylic (e.g. Perspex™) or glass, supported by the support rods R, which are extended in this embodiment. The waveguide W is arranged to concentrate light emitted by the LED's onto a smaller area with higher intensity. This arrangement is suitable for treating smaller external surfaces.

**[0054]** The second embodiment may be modified in a third embodiment, as shown in Figure 6, to deliver the light from the waveguide W into a lightguide L for internal treatment. The lightguide L, such as an optical fibre or fibre bundle, or liquid light guide, is held in a lightguide receptacle or adapter A, that is compatible for example with Olympus, Storz, ACMI or Wolf light cable fittings, in abutment or immediately adjacent relation with the narrow end of the waveguide W. The lightguide L may be of 3, 5 or 8 mm diameter. The support rods R align the optical axes of the waveguide W and lightguide L, so that the light emitted by the waveguide W is launched into the lightguide L. In the third embodiment, the light is concentrated by the waveguide and emitted over a small area at the distal end of the lightguide L which may be inserted into body cavities for oral, gynaecological, gastrointestinal or intraluminal treatment.

**[0055]** The third embodiment may be modified in a fourth embodiment, as shown in Figure 7, in which the discrete LED array is replaced by an integrated multi-die LED matrix IM (for example part no. OD 6380, OD 6624 or OD 6680 available from AMS Optotech, Bristol, UK) mounted on the support plate/heatsink P. H. A Peltier effect thermoelectric cooler PC is mounted in thermal contact with the opposite side of the support plate P, the heated side of which is cooled by the fan F. The proximal end of the lightguide L is directly adjacent or abutting the integrated LED matrix IM, which are of similar cross-section so that the waveguide is not needed to launch the emitted light into the lightguide L.

**[0056]** A fifth embodiment, as shown in Figure 8, is designed specifically for treatment of the cervix, such as PDT treatment. The fifth embodiment has the form of a hand piece having a hollow stem S, for example of acrylic or polycarbonate, through which air is blown at low pressure by a fan F mounted at the proximal end. The distal end has a head portion HP comprising a housing within which is mounted a discrete LED array mounted on a support plate/heatsink P/H. Air passes through the hollow stem S onto the heatsink H so as to extract heat therefrom and is then vented through apertures AP on the proximal side of the housing. The distal end of the housing is concave and dimensioned so as to fit closely over the end of the cervix C. A transparent end window W, for example of acrylic or glass, prevents infiltration of the LED's. Power is carried to the LED's through wires (not shown) mounted on the wall of the acrylic stem S. In use, the hand piece is positioned so that the distal end fits over the cervix of the patient and is clamped in position for the duration of the treatment.

**[0057]** The selection of appropriate discrete LED's for PDT using any of the first to fourth embodiments will now be described, grouped according to die material.

**[0058]** A first suitable type of LED is based on aluminium indium gallium phosphide/gallium phosphide (AlInGaP/GaP) of transparent substrate (TS) or absorbing substrate (AS) type. The output wavelengths are in the range 590 to 640 nm with peak emission wavelengths of 590, 596, 605, 615, 626, 630 and 640 nm. Commercially available examples are the 'SunPower™' or 'Precision Optical Power™' series from Hewlett Packard Company, designed for use in the automotive industry, for commercial outdoor advertising and traffic management. Suitable LED's are those packaged as: SMT (surface mount technology) e.g. HSMA, HSMB, HSMC, HSML series and preferably HSMB HR00 R1T20 or HSMB HA00R1T2H; Axial e.g. HLMA or HLMT series; T1 e.g. HLMP series, preferably HLMP NG05, HLMP NG07, HLMP J105; T13/4 e.g. HLMP series, preferably HLMP DG08, HLMP DG15, HLMP GG08, HLMP DD16; Superflux™ e.g. HPWA or HPWT series, preferably HPWA (MH/DH/ML/DL) 00 00000, HPWT (RD/MD/DD/BD/RH/MH/DH/BH/RL/ML/DL/BL) 00 00000, most preferably HPWT (DD/DH/DL/MH/ML/MD) 00 00000; SnapLED™ e.g. HPWT, HPWS, HP-

WL series, preferably HPWT (SH/PH/SL/PL) 00, HPWT (TH/FH/TL/FL) 00 or HPWS (TH/FH/TL/FL) 00. Suitable products from other manufacturers include: of SMT type, Advanced Products Inc. (API) part no. HCL4205AO; of T1 type, American Bright Optoelectronics (ABO) part no. BL BJ3331E or BL BJ2331E; of Superflux type, ABO part no.'s BL F2J23, BL F2J33 and BL F1F33.

**[0059]** A second suitable type of LED is the aluminium indium gallium phosphide/gallium arsenic (AlInGaP/GaAs) type, with emission wavelengths in the range 560 to 644 nm and peak emission wavelengths of 562 nm, 574 nm, 590 nm, 612 nm, 620 nm, 623 nm and 644 nm. Examples commercially available from Toshiba in T1 package are the TLRH, TLRE, TLSH, TLOH or TLYH series, preferably TLRH 262, TLRH 160, TLRE 160, TLSH 1100, TLOH 1100, TLYH 1100 or S4F4 2Q1; or in T13/4 package are the TLRH or TLSH series, preferably TLRH 180P or TLSH 180P. Another example is Kingbright L934SURC-E.

**[0060]** A third suitable type of LED is aluminium gallium arsenic type (AlGaAs), with emission wavelengths in the range 650 to 660 nm. Examples in T1 package include the Toshiba TLRA series, preferably TLRA 290P or TLRA 293P, and Kingbright L934 SRCG, L934 SRCH, and L934 SRCJ and in T13/4 package include Kingbright L53 SRCE.

**[0061]** A fourth suitable type of LED is gallium phosphide (GaP) type, with emission wavelengths in the range 550 to 570 nm.

**[0062]** A fifth suitable type of LED is indium gallium nitride (InGaN). In the type with an emission wavelength of 525 nm, commercially available examples include: in SMT package, API's HCL 1513AG; and in T1 package, Farnell's #942 467, Radio Spare's #228 1879 and #249 8752, API's HB3h 443AG and Plus Opto's NSPG500S. In the type with emission wavelengths of 470 and 505 nm and T1 package type, examples are Farnell's #142 773, Radio Spare's #235 9900 and American Bright Optoelectronics Inc.'s BL BH3PW1.

**[0063]** A sixth suitable type of LED is gallium nitride/silicon (GaN/Si), with an emission wavelength of 430 nm. One commercial example is Siemens LB3336 (also known as RS #284 1386).

**[0064]** Each of the above LED types is selected to have an emission spectrum substantially coincident with the absorption spectrum of one or more of the following common photosensitizers given below in Table 1, and therefore embodiments having such LED's are suitable for PDT. For example, Figure 9 shows the absorption spectrum of PpIX, including peaks at 505nm, 545 nm, 580 nm and 633 nm. Inset are the emission spectra, in units of peak intensity and on the same wavelength axis, of LED part no. HPWA DL00 with a peak at 590 nm and LED part no. HPWT DH00 with a peak at 630 nm, the peaks having sufficient breadth to give a substantial overlap with the 580 nm and 633 nm peaks respectively in the absorption spectrum of PpIX.

Table 1

Photosensitizer	Red absorption Band (nm)	Red Peak (nm)	Blue/Green Peak (nm)
Naphthalocyanines	780-810		
Chalcogenopyriliun dyes	780-820		
Phthalocyanines (e.g. ZnII Pc)	670-720	690	
Tin etiopurpurin (SnET <sub>2</sub> )	660-710	660-665	447
Chlorins (e.g. N-Aspartyl chlorin e6 or NPe6)	660-700	664	
Benzoporphyrin derivative (BPD)		685/690	456
Lutetium texaphrin (Lu-TeX)		735	
Al(S <sub>1</sub> /S <sub>2</sub> /S <sub>3</sub> /S <sub>4</sub> ) Pc	660-710	670/685	410,480
Photofrin		625/630	405
Protoporphyrin IX (PpIX) - from 5/δAminolaevulinic Acid (5ALA)		635	410, 505, 540, 580
Tetra m-hydroxyphenyl Chlorin (mTHPC)		650	440,525

**[0065]** The discrete LED array may comprise more than one different type of LED, each with different emission spectra, selected to match different absorption bands of the selected photosensitizer. Each type of LED may be switched independently. The penetration depth (i.e. the depth at which the intensity has been attenuated to e<sup>-1</sup>) may also be varied by switching on only one type of LED in the array so as to select a suitable emission band, since the penetration

depth is a function of the wavelength.

**[0066]** The LED array may be composed of individually switchable spatially distinct segments of LED's. Selected segments may be switched on so as to treat a selected area of the patient within the overall area of the matrix array.

**[0067]** The lamp may include an electro-optical detector arranged to monitor the light dose delivered and to switch off the light emission when a target dose is reached. Alternatively, or additionally, the detector is arranged to monitor the instantaneous light intensity and to vary the electrical power supplied to the tubes so as to maintain the intensity within predetermined limits, and/or to switch off the light emission if a maximum limit is exceeded.

**[0068]** Various different arrangements of LED array suitable for treatment of different areas of a patient will now be described. The LED's are discrete LED's as described above. Except where stated otherwise, the LED's may be fan-cooled using integrated fans.

**[0069]** Figures 10a and 10b show an array of LED's L in a sixth embodiment, arranged on a support P shaped as a curved visor for treatment of the face of a patient. The array is supported in front of the patient's face by a head band HB or other head wear worn by the patient.

**[0070]** Figures 11a to 11c show an array of LED's L in a seventh embodiment arranged within a cuboid housing HO which has two similar apertures AP on one face, to allow the elbows to be inserted into the housing HO. The edges of the apertures AP are cushioned to allow the arms to be rested comfortably. Within the housing HO is arranged a surface SU which is curved both in the plane of the arms and perpendicular to that plane, as shown in Figure 11c. The LED's L are mounted on this surface SU so that light emitted therefrom is concentrated onto the elbows of the patient.

**[0071]** Figure 12 shows an LED array L in an eighth embodiment mounted on a support plate P, and covered by a transparent or translucent cover on which the foot or feet of the patient rest during treatment.

**[0072]** Figure 13 shows an LED array L in a ninth embodiment mounted on a support plate P and arranged for treatment of the lower leg of a patient.

**[0073]** Figures 14 and 15 show an LED array L, mounted in a housing HO in the form of a trapezoid prism, the upper inner surface carrying the LED array and the lower surface being open to allow light to fall onto the patient. The side faces may be reflective, or carry additional LED arrays. In the tenth embodiment shown in Figure 14, the housing HO is mounted at one end of a bed so that its height above the bed is adjustable, for facial treatment of a patient lying on the bed. In the eleventh embodiment shown in Figure 15, the housing HO is mounted on a stand ST and is adjustable in height, for treatment of a selected part of a patient lying on the bed.

**[0074]** Figures 16a and 16b show a series of four coplanar LED arrays L in a twelfth embodiment arranged to treat one side of a patient. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

**[0075]** Figures 17a and 17b show a single LED array L in a thirteenth embodiment positioned to treat a section of the patient.

**[0076]** Figures 18a and 18b show a series of three coplanar LED arrays L in a fourteenth embodiment arranged to treat one side of a patient lying down. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

**[0077]** Figures 19a and 19b show an array of LED's L in a fifteenth embodiment mounted on the inner surface of a curved housing HO for treatment of a patient lying on a further, planar array of LED's, for treatment of a section of the patient from all sides. The housing HO is slidable along the length of the patient so as to treat a selected area of the patient. Sections of the planar array of LED's are switchable so as to illuminate only the selected section.

**[0078]** Figures 20a and 20b show a sixteenth embodiment comprising a front-facial LED array  $L_F$  for directing light onto the face of the patient from the front, a scalp LED array  $L_S$  and left and right side-facial LED arrays  $L_L$ ,  $L_R$  moveably connected, for example by hinges, to the front-facial array  $L_F$ , for directing light onto the scalp, left side of the face and right side of the face respectively. The front-facial array  $L_F$  is slideably attached to a stand ST for vertical adjustment to the head height of the patient, preferably when sitting.

**[0079]** Figure 21 shows a seventeenth embodiment, similar to that of Figures 20a and 20b, except that it is arranged for facial and/or scalp treatment of a patient when lying down. The stand ST is mounted on a bed, instead of being free-standing, and the arrays are rotated by  $90^\circ$  so as to correspond to the position of the patient's head when lying down.

**[0080]** Figures 22a, 22b and 22c show an eighteenth embodiment in which an LED array L is mounted on the inner surface of a sleeve SL so as to direct light onto the hand, forearm and/or elbow within the sleeve.

**[0081]** Figures 23a and 23b show respectively a square and a rectangular LED array L in a nineteenth embodiment mounted on a flexible backing member FB which can be applied to an area of the patient to be treated, such as part of the forearm as shown in Figure 23c, with the LED's facing inwardly. The LED array thereby follows the contours of the area to be treated. The flexible backing member FB may be cooled by a fan which is either discrete or connected thereto by a flexible membrane which is fixed around the flexible backing member FB and directs air from a fan onto the backing member, through which the air is vented.

**[0082]** Figure 24 shows an LED array in a twentieth embodiment arranged on the surface of a cylindrical intraluminal

probe, while Figure 25 shows an LED array in a twenty-first embodiment arranged on the surface of a spherical head of an intraluminal probes. The probes are dimensioned for vulval, cervical, endometrial, bladder, gastrointestinal, oral, nasal, aural and/or bronchial treatment.

[0083] In tests performed by the inventor, the efficacy of PDT using red (approximately 630 nm) emission from LED's was established in *in-vivo* comparative studies using a sub-cutaneous mammary tumour regrowth delay assay. Using radiobiological end-points, it was shown that the solid-state prototype efficacies were comparable to that of expensive conventional lasers for PDT (i.e. no significant difference,  $p=0.21$ ). These results were confirmed in further clinical studies in the treatment of Bowen's disease and basal cell carcinomas where comparative complete response rates were achieved as compared to laser PDT.

[0084] Figure 26 shows a more specific example of the nineteenth embodiment, consisting of rows of blue LED's  $L_B$  interspersed with rows of red LED's  $L_R$  so as to form a discrete LED array composed of different types of LED as described above. The blue LED's  $L_B$  are switchable on and off together, independently of the red LED's  $L_R$  which are also switchable on and off together. In this way, red or blue illumination may be chosen according to the type of treatment and penetration depth required.

[0085] The blue LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 370 to 450 nm, and preferably 400 to 430 nm. This range is particularly suitable for the treatment of pre-cancerous conditions, in particular actinic keratoses.

[0086] The red LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 620 to 700 nm. This range is particularly suitable for the treatment of non-melanoma, such as basal cell or squamous cell carcinoma, or mycosis fungoides.

## Claims

1. A light source for therapy and/or diagnosis, comprising a first rigid array of light-emitting diodes, a second rigid array of light emitting diodes movably connected to an edge of the first array and a third rigid array of light-emitting diodes movably connected to another edge of the first array, wherein each said array is arranged so that light from the light-emitting diodes is incident directly in the treatment field and includes means for cooling the diodes by forced air convection.
2. A light source as claimed in claim 1, further including a fourth array of light-emitting diodes movably to a further edge of the first array.
3. A light source as claimed in claim 1 or 2, arranged for treatment of the face and/or scalp.
4. A light source as claimed in any preceding claim, wherein each said array is arranged so that light from the light-emitting diodes is incident directly in the treatment field with an output intensity of at least 10 mW/cm<sup>2</sup> and a spatial intensity fluctuation of 10% or less.
5. A therapeutic light source, comprising an array of light-emitting diodes arranged so that light from the light-emitting diodes is incident directly in a treatment field, having an extent approximately equal to that of the array of diodes, with an output intensity of at least 10 mW/cm<sup>2</sup> and a spatial intensity fluctuation of 10% or less, and means for cooling the diodes by forced air convection.
6. A light source as claimed in claim 4 or 5, wherein the spatial intensity fluctuation is 6% or less.
7. A light source as claimed in any preceding claim, wherein the light-emitting diodes are mounted discretely.
8. A light source as claimed in claim 7, wherein the light-emitting diodes are electrically connected in a parallel-series matrix.
9. A light source as claimed in any preceding claim, wherein the light-emitting diodes are thermally coupled to one or more heatsinks.
10. A light source as claimed in claim 9, wherein the diodes are thermally coupled to an array of individual heatsinks.
11. A light source as claimed in claim 10, wherein the light-emitting diodes and the heatsinks are mounted on a support plate.

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12. A light source as claimed in claim 11, wherein the light-emitting diodes and the heatsinks are mounted on opposite sides of the support plate.

13. A light source as claimed in claim 11 or claim 12, wherein the support plate is perforated to allow air to flow around the heatsinks and light-emitting diodes.

14. A light source as claimed in any preceding claim, wherein light from the light-emitting diodes is not concentrated by any optical system.

15. A light source as claimed in any preceding claim, wherein the light emitting diodes have emission wavelengths substantially in a range of 370 to 450 nm.

16. A light source as claimed in claim 15 wherein the light emitting diodes have emission wavelengths substantially in a range of 400 to 430 nm.

17. A light source as claimed in any one of claims 1 to 14 wherein the light emitting diodes have emission wavelengths substantially in a range of 550 to 660 nm.

18. A light source as claimed in claim 17 wherein the light emitting diodes have emission wavelengths substantially in a range of 590 to 640 nm.

19. A light source as claimed in any one of claims 1 to 14 wherein the light emitting diodes have emission wavelengths substantially in a range of 550 to 660 nm.

20. Use of a light source as claimed in any preceding claim, for cosmetic treatment of a patient.

21. Use as claimed in claim 20, wherein the treatment comprises skin rejuvenation.

22. Use as claimed in claim 20, wherein the treatment comprises wrinkle removal.

23. Use as claimed in claim 20, wherein the treatment comprises biostimulation.

Fig. 1

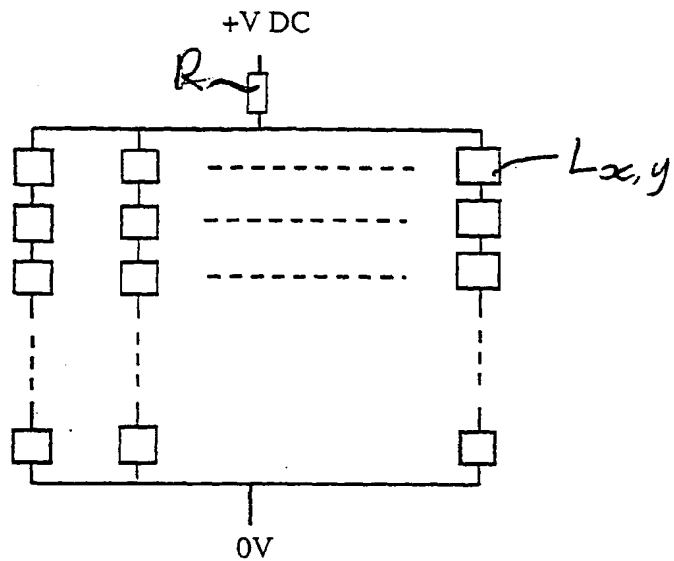


Fig. 5

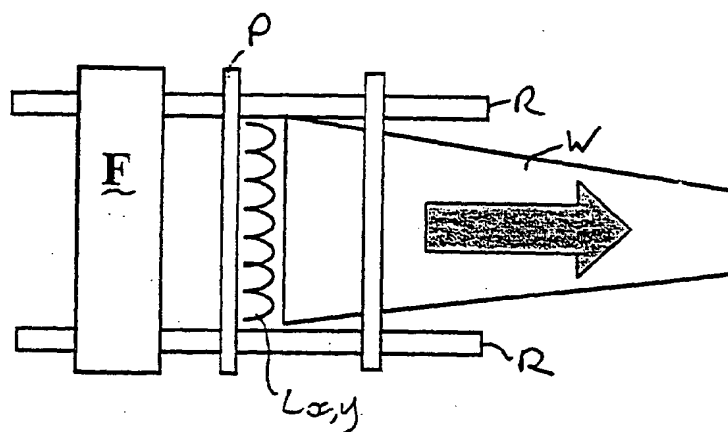


Fig. 2

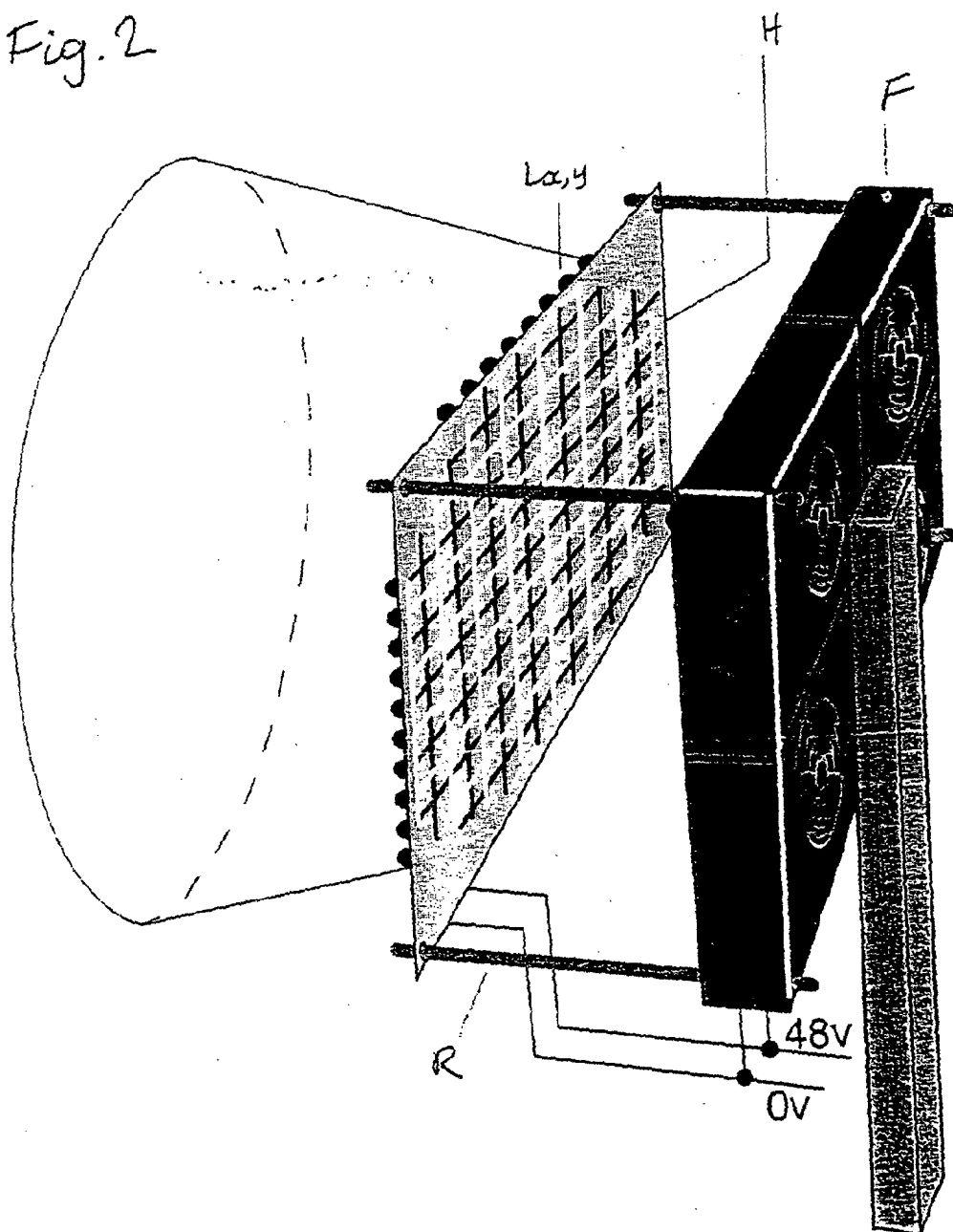




Fig. 3

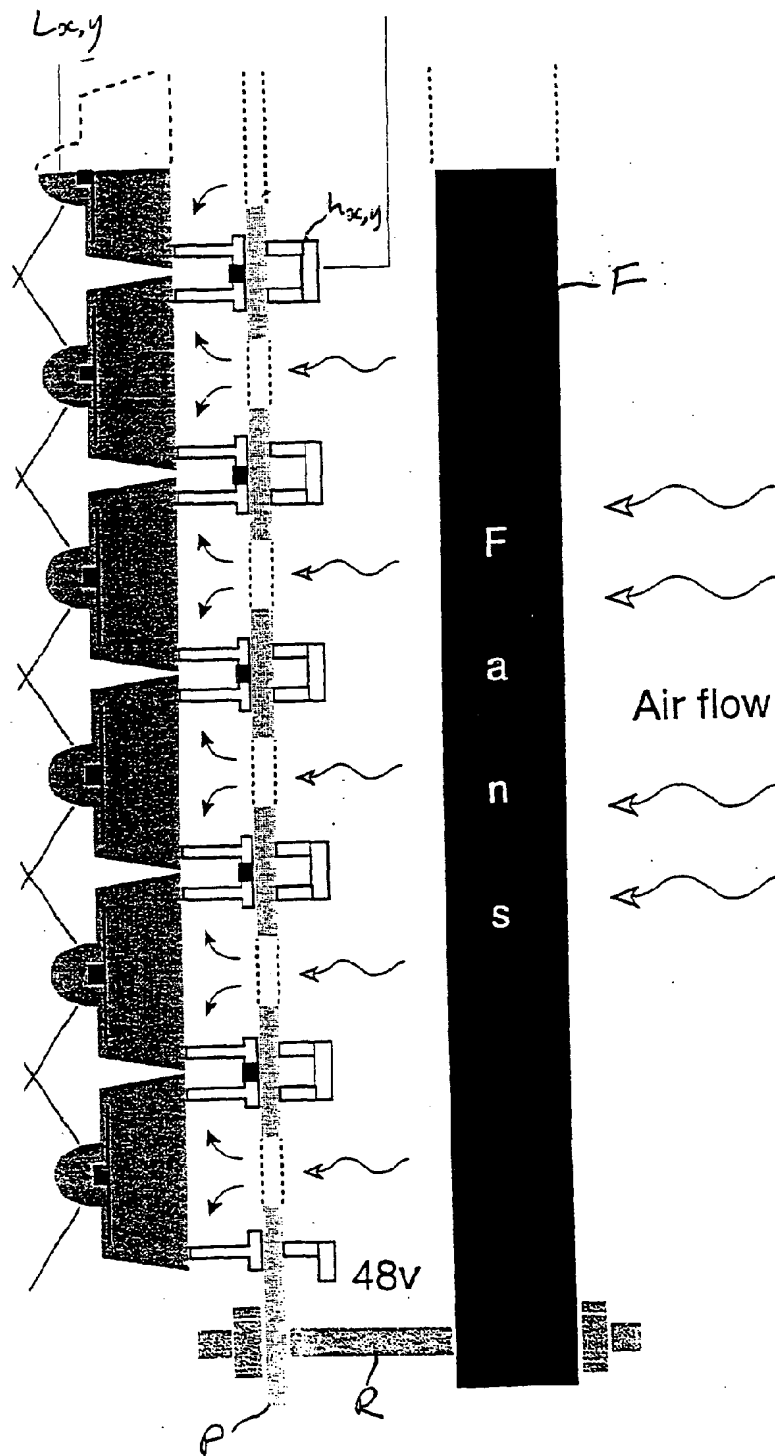


Fig. 4

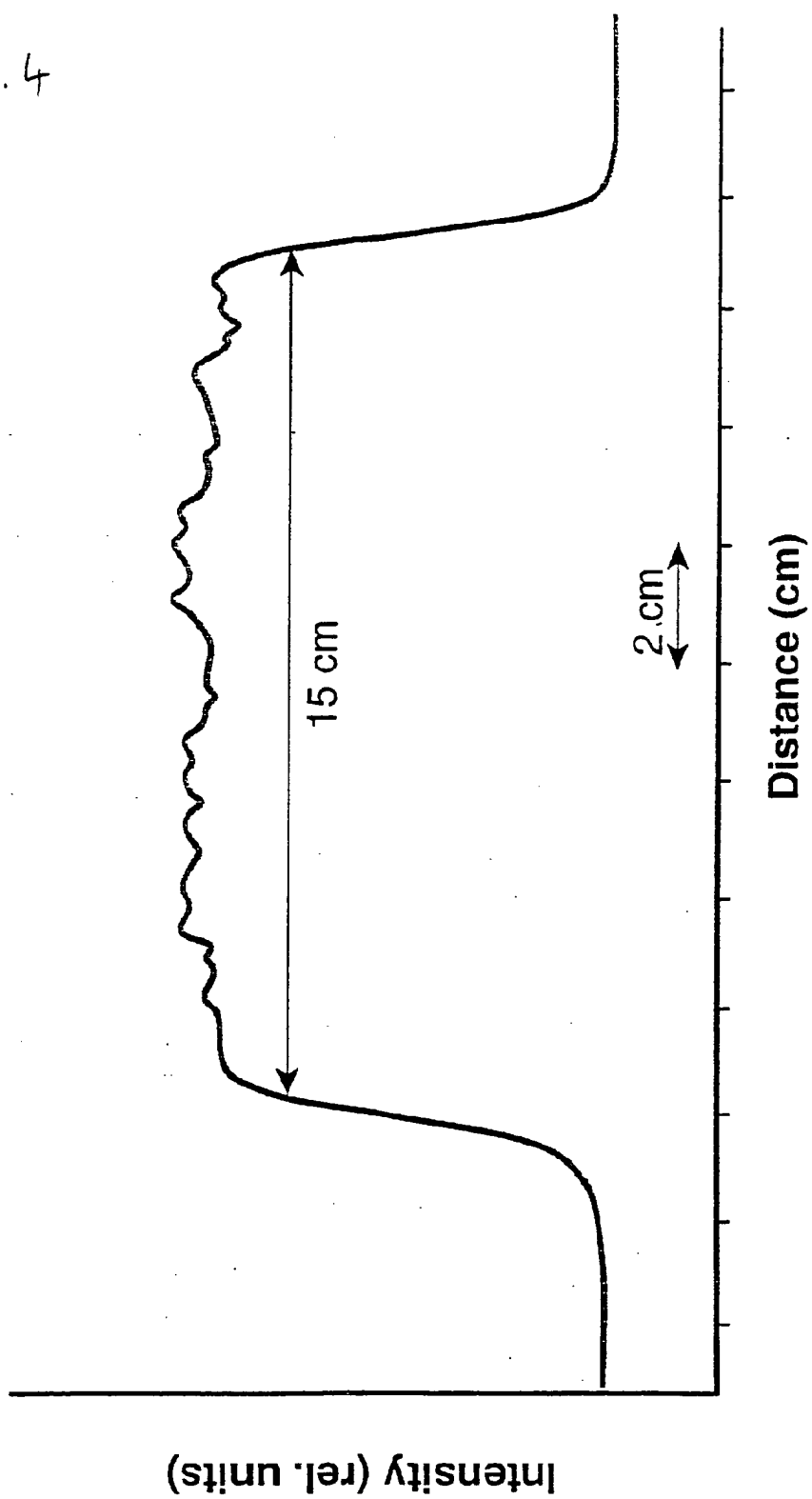


Fig. 6

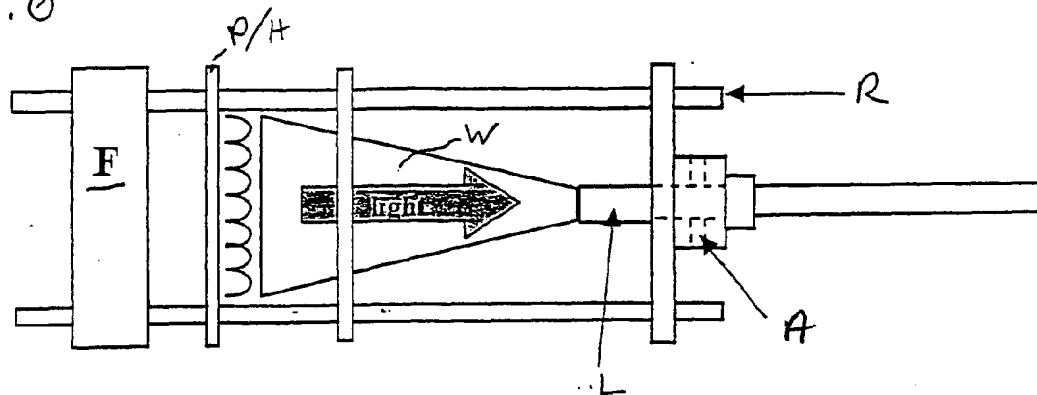


Fig. 7

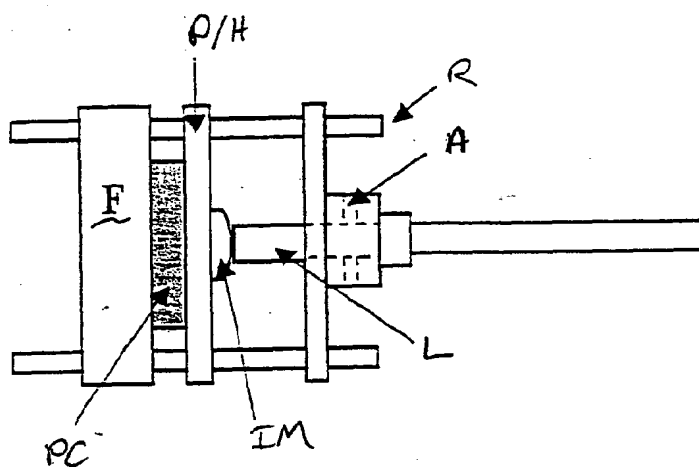
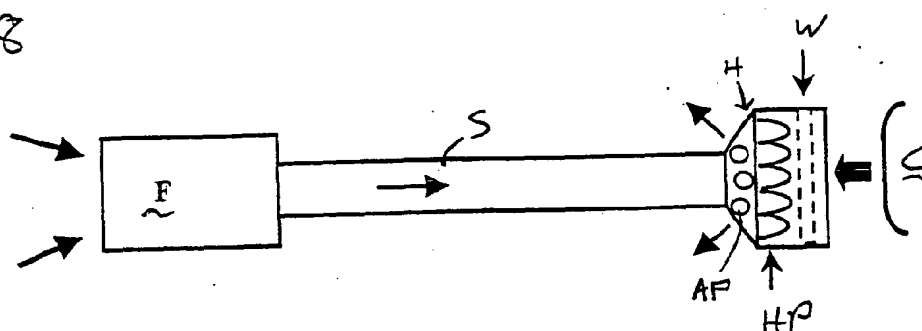


Fig. 8



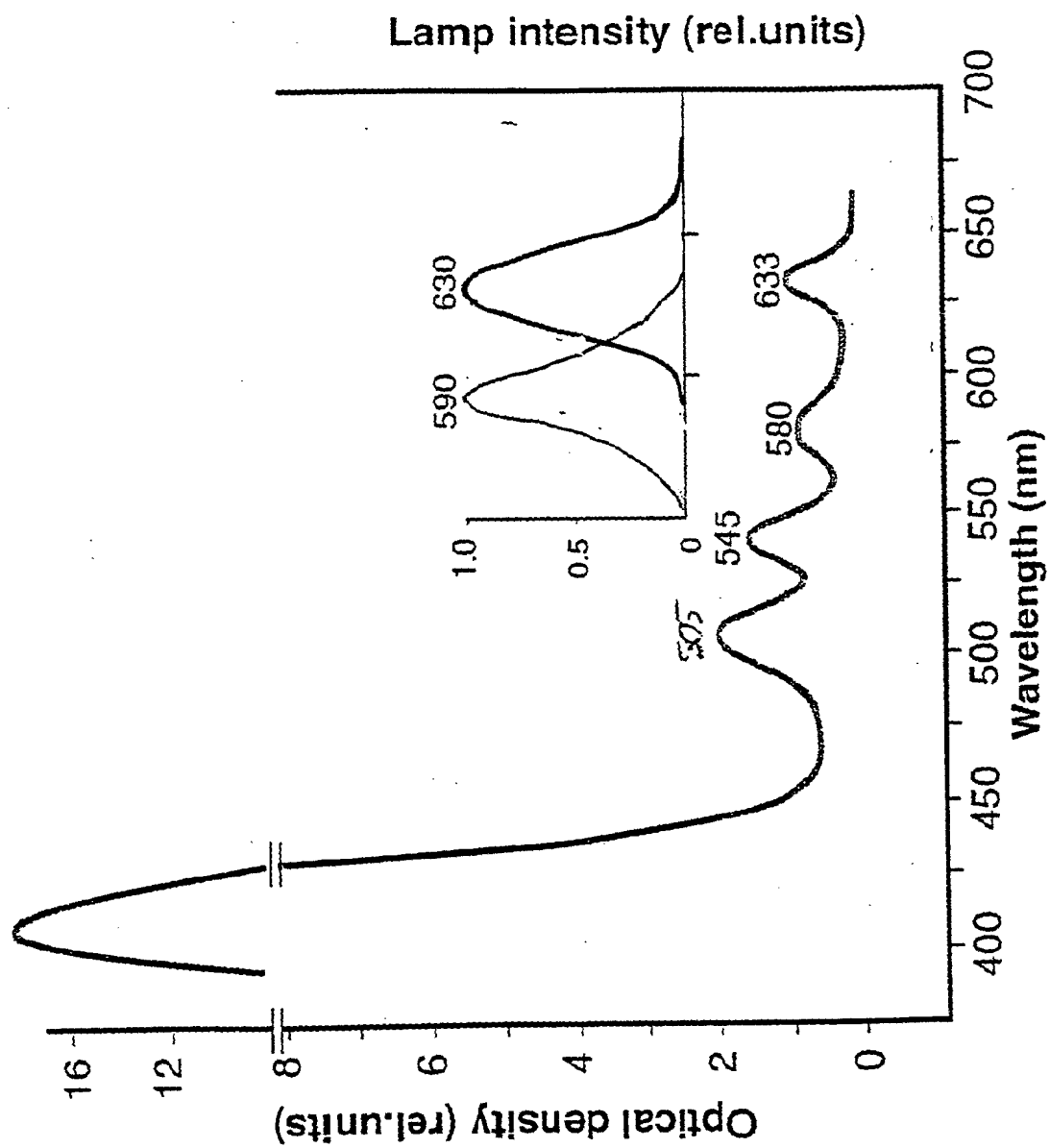


Fig. 9

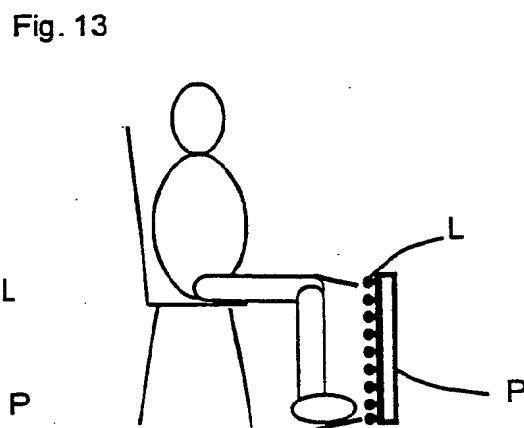
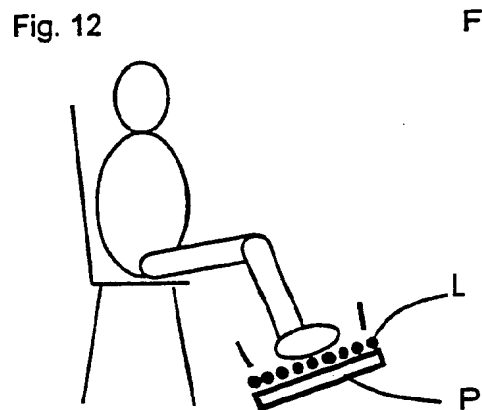
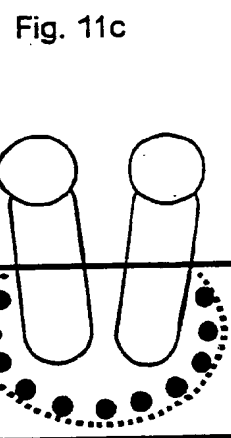
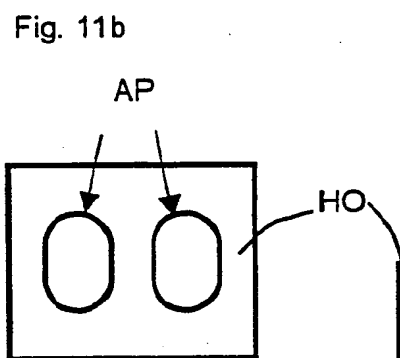
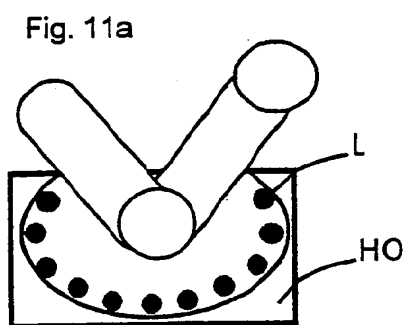
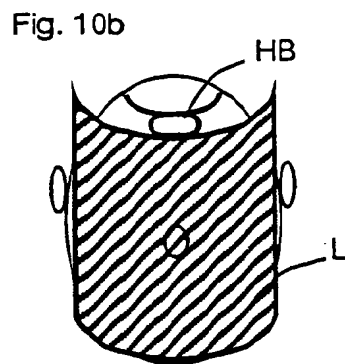
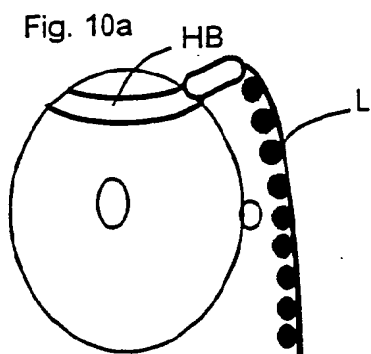


Fig. 14

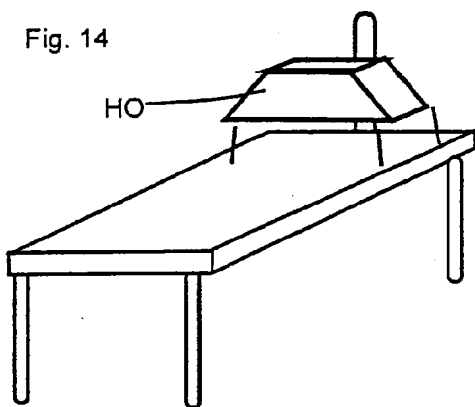


Fig. 15

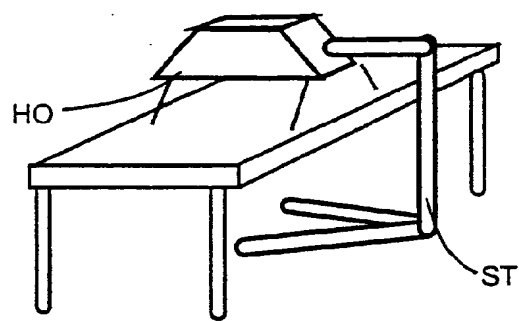


Fig. 16a

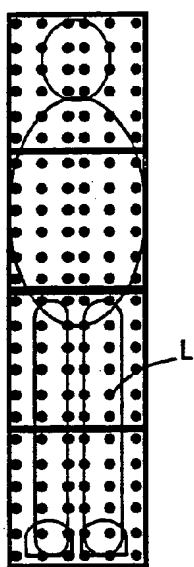


Fig. 16b

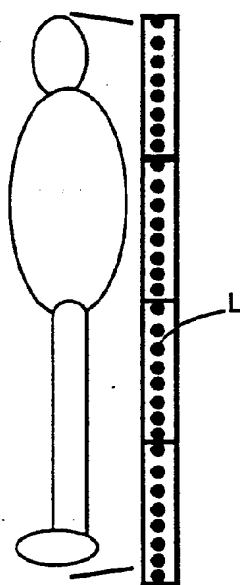


Fig. 17a

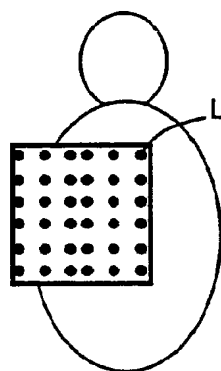


Fig. 17b

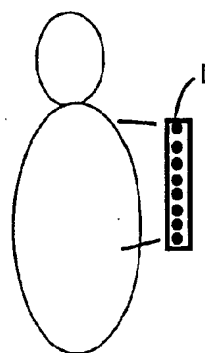


Fig. 18a

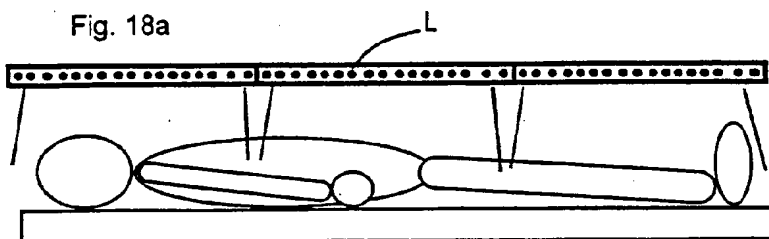
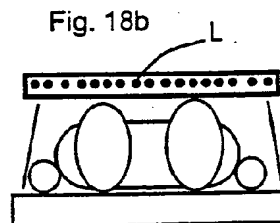
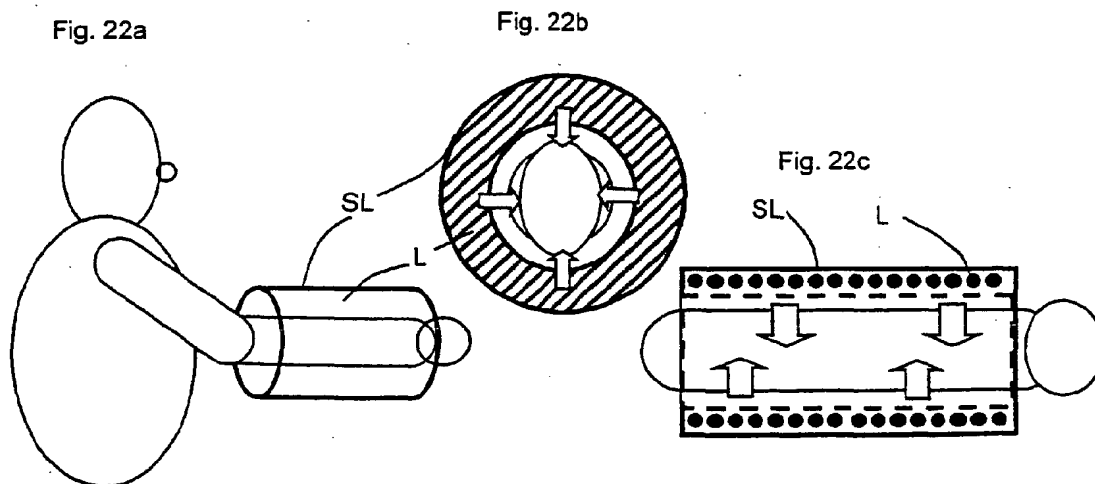
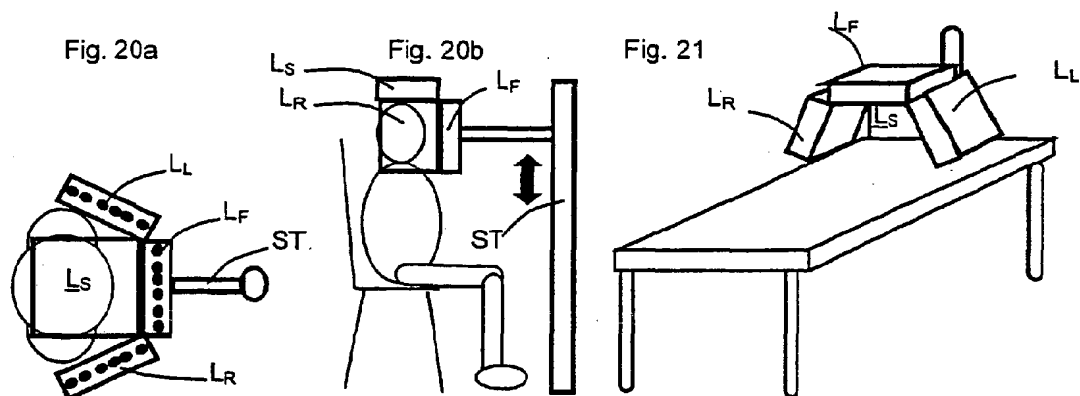
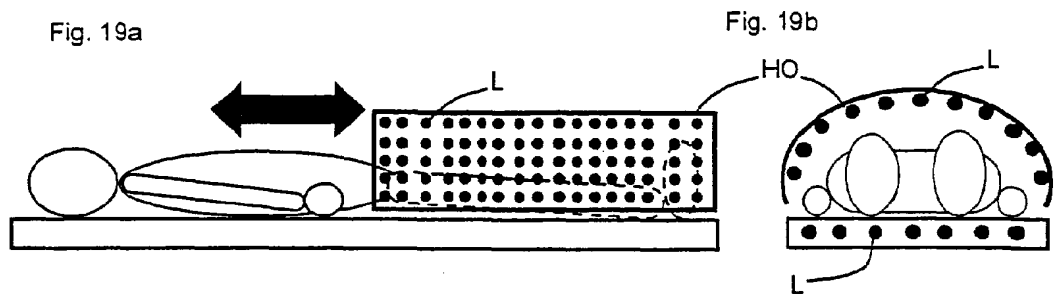
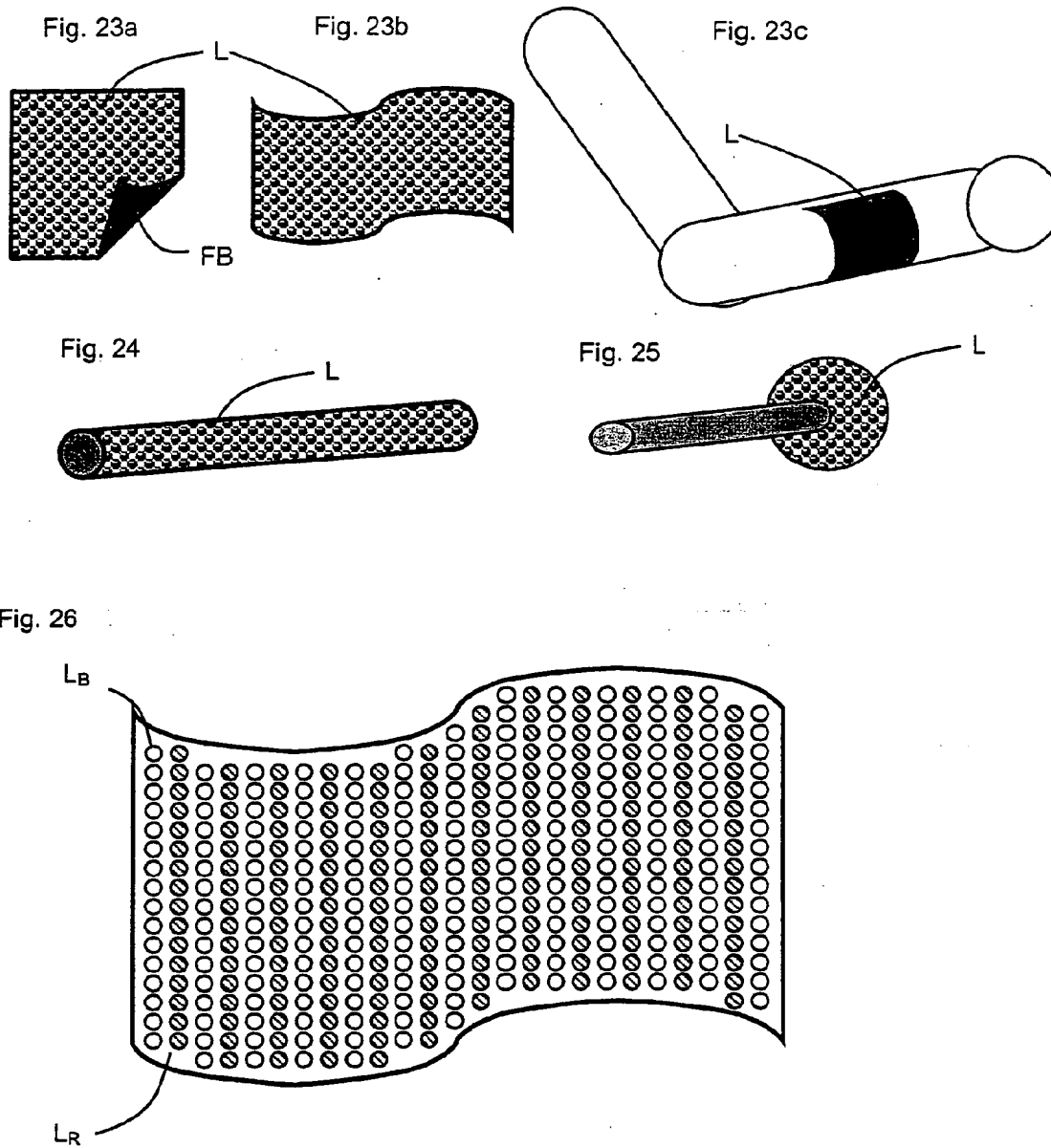


Fig. 18b











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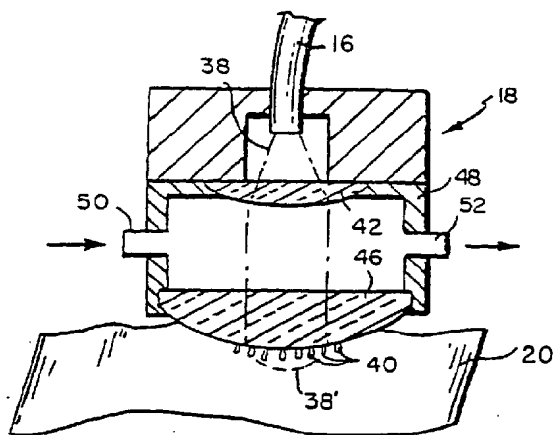
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Remarks:

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under INID code 62.

(54) **Hair removal apparatus using optical pulses**

(57) Apparatus for simultaneously effecting the removal of multiple hairs from a skin region 20 by using light energy to destroy hair follicles 40 in the region is disclosed. Light energy is applied to the region through an applicator 18 which converges the light energy to enhance destruction of desired portions of the follicles, is preferably pressed against the skin region to deform the upper layers of the skin reducing the distance from the skin surface to portions of hair follicles which are to be destroyed, including the bulge and papilla of the follicles, and which applicator is preferably cooled 50, 52 to minimize or eliminate thermal damage to the epidermis in the region being irradiated. Parameters for the irradiation, including pulse duration, are selected to effect complete damage of desired portions of the hair follicles in the region with minimal damage to surrounding tissue and to the patient's epidermis.



**FIG. 2A**

**Description****Background**

5 [0001] This invention relates to apparatus for hair-removal using optical radiation.

[0002] Excess hair (hypertrichosis) and/or unwanted hair are common dermatological and cosmetic problems, and can be caused by heredity, malignancy, or endocrinologic diseases, for example hirsutism (i.e., excess hair due to hormones such as androgens). Hair can be temporarily removed using a number of techniques including wax epilation, depilatory creams, and, of course, shaving. Alternatively, hair can be more permanently removed using electrolysis; this process involves insertion of a current-carrying needle into each hair follicle, and is often painful, inefficient, and time consuming.

[0003] Optical-based methods, such as the use of laser light, have also been used for hair removal. US-A-4 388 924, for example, describes irradiation of individual hair follicles using a laser; in this method, heating of the hair's root section causes coagulation in local blood vessels, resulting in destruction of the follicle and thus in removal of the hair. Related techniques, such as those described in

[0004] US-A-5 226 907, involve destruction of the follicle by first applying a light-absorbing substance to the region of interest, the light-absorbing substance migrating at least part-way into the follicle, removing the excess light-absorbing substance, and then irradiating the region to heat the substance and thus the follicle to cause destruction of the follicle.

[0005] The above prior art techniques suffer from a number of limitations. First, techniques for irradiating an individual hair follicle are time consuming and therefore are generally not practical for removing hairs other than from a very small region or from a region having few hairs situated therein. The procedure can also be painful, particularly if a needle-like element is inserted into the hair follicle to facilitate light energy reaching the bulge and the root or papilla, parts of the hair follicle which must be destroyed in order to prevent regrowth of the hair. Where the irradiation source is not inserted into the follicle, it is difficult to get sufficient energy to the required portions of the follicle to result in destruction thereof without also causing significant damage to the surrounding tissue and thus causing pain and injury to the patient.

[0006] While the technique of the latter patent is advantageous in that it permits a number of hairs in a given region to be simultaneously removed, it is difficult with this technique to get the light-absorbing substance or chromophore deep enough into the follicle to effect destruction of the papilla. Further, this technique results in substantial energy being applied to and absorbed by the epidermis and other skin layers in the region being treated, with significantly reduced energy reaching the root or papilla of the follicle. Total destruction of the follicle, and therefore permanent, or at least long term, hair removal is therefore difficult to achieve, particularly without risking damage to the epidermis and other layers of skin within the region.

[0007] A need therefore exists for improved apparatus for performing hair removal which facilitates optical energy reaching the bulge and base, or root of hair follicles in a region while minimizing damage to the epidermis in the region, thereby minimizing patient discomfort and potential adverse side effects from the treatment.

**Summary of the invention**

40 [0008] The present invention provides in a first aspect apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising: an applicator;

a source of optical radiation; and

45 an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region, characterised in that the said radiation has a wavelength between 680nm and 1200nm, preferably between 680nm and 900nm, and a fluence of between 10J/cm<sup>2</sup> and 200J/cm<sup>2</sup>, and in that the duration of the radiation on the said skin region is 50µs to 200ms, preferably 5ms to 200ms.

[0009] In a second aspect the invention provides apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising an applicator, which preferably comprises a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed; a source of optical radiation; and

50 an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region,

characterised in that the apparatus further comprises means for cooling the said surface of the applicator to a temperature below that of the said skin region.

[0010] In a third aspect, the invention provides apparatus for the simultaneous removal of a plurality of hairs from a

skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising an applicator comprising a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed; a source of optical radiation; and an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region, characterised in that at least the said surface of the applicator is formed of a material having a refractive index which substantially matches the refractive index of the skin surface in the said skin region.

**[0011]** In a fourth aspect, the invention provides apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising: an applicator comprising a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed; a source of optical radiation; and an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region, characterised in that further comprising an element in the optical path for converging the optical radiation as it leaves the applicator through the said surface.

**[0012]** In a fifth aspect, the invention provides an applicator suitable for use in practising a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin, from a skin surface, comprising: a housing; a transmitter of optical radiation into said housing; a surface disposed on the housing having a convex shape and adapted to be in pressure contact with the skin surface in the said skin region; an optical path through said housing from the transmitter of optical radiation to the said surface which path is substantially transparent to optical radiation at the said selected wavelength; an element in the optical path for converging the optical radiation as it leaves the applicator through the said surface; and means for cooling the said surface to a temperature below that of the said skin region.

**[0013]** The technique of using the apparatus of the invention involves placing the applicator in contact with the skin surface in the skin region and applying optical radiation of a selected wavelength and of a selected flux through the applicator to the skin region for a predetermined time interval. The applicator is preferably pressed against the skin surface, thereby reducing the distance from the applicator to the papilla of the hair follicles and facilitating destruction thereof. Further, the skin surface in the skin region can be cooled to a selected depth during the applying of optical radiation to the skin region and/or prior thereto. This allows the papilla of the hair follicles to be significantly heated without damage to the skin surface in the skin region up to the selected depth.

**[0014]** In some embodiments, the applicator is utilized to cool the skin surface in the skin region to the selected depth and the selected depth is preferably at least equal to the depth of the epidermis layer of the skin (i.e., the layer of the skin closest to the skin surface). The cooling by the applicator may for example be accomplished by cooling at least the surface of the applicator in contact with the skin surface, such cooling preferably being accomplished both before and during the irradiation of the skin. Preferably, the cooling of the applicator is accomplished by passing a cooling fluid such as water through the applicator, preferably through a channel near the surface. It is preferred that irradiation of the skin surface not be performed until the skin region has been cooled to substantially the selected depth. Most preferably, cooling is performed both before and during irradiation, and the selected flux and predetermined exposure time (i.e., time interval for irradiation) are selected such that there is at most minimal heating of skin in the skin region to the selected depth, while there is sufficient heating of hairs and follicles below the selected depth to at least damage the hairs and follicles without causing significant damage to tissue surrounding the follicles. A preferred time interval for irradiation is 2ms to 100ms.

**[0015]** In some embodiments, the applicator converges optical radiation applied to the skin region, thereby further facilitating irradiation of the follicle papillas. Preferably the element in the applicator which converges the radiation is a lens. In preferred embodiments, the applicator also has a convex surface in contact with the skin surface, applying substantially uniform pressure thereto to deform the underlying skin surface. In other embodiments, the applicator is designed to form a fold of the skin in the skin region and to apply optical radiation to two substantially opposite sides of the fold. For example, the applicator may have a slot formed in the surface thereof in contact with the skin surface, with at least a portion of the skin region being drawn up into the slot and optical radiation being applied to the skin region from at least two opposite sides of the slot.

**[0016]** In some embodiments a substantial refractive index match be maintained between the applicator and the skin surface in said skin region. Such refractive index match may be provided by a layer of refractive index matching substance between the applicator and the skin surface in a skin region and/or by forming the applicator of a material which at least for the surface in contact with the skin region has a refractive index which substantially matches that of the skin surface.

**[0017]** To facilitate hair removal, hairs in the skin region may be shaved prior to irradiation. However, it may be preferable to epilate the hairs in the skin region before irradiation. When hairs are epilated, destruction of the follicles can be facilitated by filling the follicles from which the hairs have been epilated with a substance which preferentially

absorbs optical radiation at the selected wavelength being used for irradiation (i.e., a chromophore). Further, where only temporary hair removal is desired, this may be accomplished for a period of up to several weeks, relatively painlessly, by applying the chromophore to the area, which has been preferably pre-shaved, which chromophore migrates into the hair follicles to a depth of a few millimeters, roughly to the depth of the sebaceous gland. Low level irradiation applied through the applicator to the skin region will then result in the destruction of the hair without destroying the follicle.

**[0018]** In one embodiment, the surface of the applicator in contact with the skin has a convex shape while in another embodiment the surface has a slot formed therein, with the optical path leading to at least two opposite sides of the slot, and the applicator includes a means for drawing at least a portion of the skin region into the slot, this means for drawing preferably includes a vacuum applying element.

### Brief description of the drawings

**[0019]** The invention will be further described, by way of example with reference to the drawings, in which:

Fig. 1 is a perspective view of a laser-based hair-removal device according to the invention;

Figs. 2A and 2B are cross-sectional views of an irradiating unit or applicator suitable for use with a hair-removal device of the invention, the applicator receiving, respectively, light from a fiber optic or fiber optic bundle, and from a mirror assembly;

Figs. 3A, 3B, and 3C are, respectively, an expanded, cross-sectional view of the contact device of the irradiating unit in direct contact with a hair-containing skin region, a cross-sectional, cut-out view showing the back-scattered optical fields at the contact device/epidermis interfacial region, and a cross-sectional cut-out view showing thermal transport at the interfacial region;

Fig. 4 is a plot showing the optical absorption spectra of melanin, hemoglobin, oxygenated hemoglobin, and water; Figs. 5A and 5B show, respectively, the time and spatial profiles and the preferred optical field used during the hair-removal process;

Fig. 6 is a plot of the computer-generated optical intensity as a function of skin depth for different optical fields;

Fig. 7 is a photograph showing skin regions of a patient three months after being treated according to the hair removal method of the invention;

Figs. 8A, 8B and 8C are oscilloscope traces showing, following irradiation, the time-dependent temperature responses of, respectively, dry black hair, wet black hair, and live skin surrounding the black hair sample;

Fig. 9 is a plot showing the temperature rise as a function of laser pulse energy for dry hair (DH), wet hair (WH), and skin (S) samples of eight different patients;

Fig. 10A is a partial cross-sectional view of an applicator of the invention being used to practice an alternative embodiment of the invention wherein epilation and filling of empty follicles with a chromophore are performed before irradiation; and

Fig. 10B is a cross-sectional view of an applicator according to another embodiment being used for hair removal.

### Detailed Description

**[0020]** Referring to Fig. 1, an exemplary laser-based hair-removal system 10 includes a light source 12, which may, for example, include one or more lasers for generating the irradiating field. The light source 12 may be optically coupled to a series of beam-manipulating optics 14 which, in turn, may be coupled via a fiber optic cable 16 (or other fiber optic device) to the irradiating unit or applicator 18. During the hair-removal therapy, the light source is powered by a voltage and current supply 19, and delivers a beam of light through the optics 14 and fiber optics 16 to the irradiating unit or applicator 18. The field is then delivered to a region 20 of a patient 22 (positioned, for example, on a table 25, a chair, or other suitable positioning element depending on the location of the region 20 on the patient's body) resulting in hair removal from the region 20. Once the desired region is treated, the irradiating unit can be easily moved along the patient 22, as indicated by arrows 27, and used to treat subsequent regions.

**[0021]** The spatial and temporal properties of the optical field determine the efficacy of the hair-removal process, and some of these properties may, if desired, be adjusted using a series of controls 24, 26, 28 located on various components of the hair-removal system 10. For example, using controls 24 located on the power supply, the optical intensity and pulse repetition rate of the irradiating field can be controlled by adjusting parameters such as the voltage, current, and switching rate for the laser's power supply. Other properties of the field, such as the wavelength and pulse duration, may be varied by controls 26 which adjust components (e.g., gratings, mirror or filter positions, shutters, or pulse-forming means) of the light source 12; however, for preferred embodiments wavelength would not be adjusted. Similarly, controls 28 can be used to adjust the modulating optics 14, resulting in control of properties such as mode quality, beam diameter, and coupling of the irradiating field into the fiber optics 16. All controls may be adjusted by

hand; and the system may also be operated (i.e., the laser turned on) by hand or, alternatively, by using a foot pedal 30 connected to the system 10.

**[0022]** In alternate embodiments, the light source, coupling optics, and irradiation unit may be encompassed in a single, hand-held device. In this case, the light source is preferably an array of diode lasers coupled directly to the irradiating unit, and is powered by a small external power supply. The compact nature of this type of optical system allows for a more controllable, manoeuvrable device, and additionally obviates the need for fiber optic delivery systems.

**[0023]** In order to effectively destroy the irradiated hair follicles without causing damage to the surrounding skin, the light field supplied by the system 10 and the irradiating unit 18 is designed to maximize the amount of light-induced heat deposited in the hair follicles, while reducing the degree of injury to the surrounding skin. It is preferred, for example, to deliver sufficient optical energy to several "target" regions on the hair follicle; radiation delivered to these regions results in complete and localized destruction of the follicles.

**[0024]** Prior to treatment, the region to be treated may be shaved in order to facilitate irradiation of the follicles. Alternatively, as will be discussed later, hairs in the region may be epilated and a chromophore may be applied to region 20, which chromophore migrates into the empty follicles. Excess chromophore may then be removed from the skin surface prior to irradiation. Prior to treatment, an anaesthetic may also be injected locally or applied to the skin surface and following treatment, patients may be treated with topical antibiotic ointments.

### Mechanical structure

**[0025]** With reference now to Figs. 2A and 2B, the applicator or irradiating unit 18 of the hair-removal system allows delivery of the irradiating field 38 to hair follicles 40 located in the region 20. As shown in Fig. 2A, the field 38 may be delivered to the irradiating unit 18 using a fiber optic cable 16 (or other fiber optic device) containing one or more fibers or fiber optic bundles. In this case, after exiting the waveguide, the field 38 is typically spatially dispersed, and is preferably collected and roughly collimated using a plano-convex lens 42. Alternatively, as shown in Fig. 2B, the field may be delivered to the irradiating unit using, for example, one or more reflecting mirrors 44. This allows the field 38 to be roughly collimated prior to impinging on the lens 42. Depending on the focal length of the lens 42 and the mode quality of the irradiating field, the field is preferably condensed using, e.g., a plano-convex lens as shown in the figure. After passing through this optic, the beam then impinges on a lens or contact device 46 which is placed in contact with the skin region 20. The optical and mechanical properties of the contact device 46 are chosen to allow efficient coupling of the optical radiation into the skin region (resulting in a delivered field 38) and the thermal properties of the contact device are chosen to allow efficient coupling of heat from the skin region. Once delivered, the field is used to irradiate, heat, and then destroy the hair follicles 40. The contact device 46, in addition, is used to couple light and heat out of the superficial skin layer (i.e., epidermis) of the irradiated region. This allows the light-absorbing pigment (i.e., melanin) contained within the deep part of the hair follicles to be irradiated and selectively heated, permitting permanent destruction of the follicle, while potentially deleterious optical and thermal energy are simultaneously conducted out of the overlying skin layers. Thus, multiple hair follicles can be destroyed, permanently removing hair from the skin region without causing substantial pain or injury to the patient. The destroyed follicles are ultimately removed by the body.

**[0026]** Both the lens 42 and contact device 46 are preferably disposed in a housing 48 containing both entrance 50 and exit 52 ports for fluids such as cooling water and pure gas (i.e., nitrogen to prevent condensation on the lens) to flow into and out of; fluids may be used, for example, to cool the contact device 46, which, in turn, cools the skin surface. Alternatively, the housing 48 may include an electrically controlled cooler in order to provide accurate control over the temperature of the contact device 46. Preferably, when cooling means are used, the temperature of the surface layer or epidermis of the skin is reduced to between 4-15°C. In addition, in this case, it is preferred that a short time period (e.g., about 1 second) be allowed to elapse before irradiation in order to ensure that the epidermis is adequately cooled. An external casing 39, as indicated in Fig. 2B by the dashed line, or a fiber-coupling housing 37, as shown in Fig. 2A, may be used to connect the light-delivering means to the housing 48.

**[0027]** With reference now to Fig. 3A, the contact device 46 is preferably formed into a lens shaped in order to converge the irradiating field, preferably near the base of the hair follicles 40. In order to converge light, the contact device must be optically transparent at the irradiating wavelength, and preferably has a biconvex or plano-convex lens shape, preferably with an f number less than or equal to f/1.0, and a focal length of between about 0.5cm and 2cm. Control over the surface shape of the contact device allows the converged light field 38' to simultaneously irradiate various target portions of the hair follicle, resulting in efficient destruction. Typically, each irradiated hair shaft has a diameter of about 75 µm, with the entire follicle having a diameter of about 200 µm. After passing through the contact device 46, the light field 38' is preferably converged through the epidermis 56 of the skin layer (having a thickness, e.g., of about 0.1mm) and is condensed in the dermis 58 near the papillae 54 of the follicles 40. Because dermal thickness varies greatly over the body, the papillae may be superficial (as in, e.g., the eyelids and scrotum), but for most areas of interest (e.g., the face, axillae, and legs) the papillae are located at depths of approximately 4mm to 7mm beneath the epidermal surface. Located a few tenths of a millimeter below the papillae are neurovascular bundles 60 which

serve the metabolic and other needs of a hair matrix, the region of rapidly growing keratinizing cells, located in the papilla, which produce the hair shaft 55. The matrix, papilla, and the corresponding vascular bundle, as well as the bulge near the center of the follicle, represent the follicular targets to be irradiated/destroyed. Preferably, during irradiation of these regions, the field is pulsed, the pulse duration of the irradiation being kept short enough so that damage is localized to a small region of dermis (typically within about 0.2mm) surrounding each follicle in accordance with the principles of selective photothermolysis. The extent of damage is preferably much less than half the distance between neighboring follicles (typically between 1mm and 4mm); if it is significantly greater than this, the light-induced injury may result in a third-degree burn.

**[0028]** In addition to providing a light converging function, a contact device 46 having a convex-shaped surface 62 allows efficient compression of the skin during contact. Compression of the dermis 58 located near the surface 62 of the contact device decreases the distance between this region and the papillae; depending on the force applied, the distance may be decreased by up to several millimeters. Because the radiation field 38' is scattered and correspondingly attenuated during propagation through the dermis, compression of the skin results in bringing more light to the deep portions of the hair follicles for more efficient light-induced heating of the papilla. In addition, compression of the dermis by the contact device using a pressure greater than the patient's blood pressure forces light-absorbing blood out of the irradiated region (indicated during treatment by a whitening of the skin in the pressurized region). This reduces absorption of the optical field, resulting in more efficient delivery of light to the follicular target regions. Pressure applied using a contact device having a convex surface results in a relatively uniform displacement of blood from the skin region. A contact device having this shape is therefore preferred to a flat device, which tends to produce regions having center portions which are not entirely blood-free.

**[0029]** In alternate embodiments, the contact device may be mounted in the housing in a spring-loaded fashion so that it may be forced against the skin surface with an adjustable pressure. In addition, in this embodiment, the spring mechanism may be attached to a sensor and readout device so that the exact pressure applied to the skin surface can be accurately monitored and/or controlled.

**[0030]** When forced against the skin, the contact device 46 allows optical radiation to be coupled into and out of the epidermis. With reference now to Fig. 3B, the refractive index ( $n_{CD}$ ) of the contact device 46 should be approximately matched to that ( $n_{EP}$ ) of the epidermis 56, which is approximately 1.55. Because light travelling from one refracting medium (i.e., the contact device) to another (the epidermis) is reflected at the interface 57 separating the two regions by an amount related to the square of the refractive index difference, nearly index-matching allows efficient coupling of the irradiating field into the skin. Thus, a contact device composed of a material having a refractive index near 1.5 or somewhat greater allows the incident irradiating field to undergo minimal reflections (indicated in the figure by the arrow 64) at the epidermis/contact device interface 57. Similarly, as indicated in the figure by the arrows 66, optical fields within the dermis are back-scattered towards the epidermis due to diffuse reflectance. These back-scattered fields contribute to unwanted epidermal heating, and are easily coupled out of the skin using the index-matched contact device 46. This allows minimization of the light-induced damage to the epidermis 56, while allowing effective irradiation of the follicle target sites within the dermis. In preferred embodiments, in order to be substantially index-matched, the contact device is preferably formed of a high-density material such as sapphire ( $n_{CD}=1.7$ ), fused silica ( $n_{CD}=1.5$ ), or similar optically transparent glasses or plastics. In order to provide a convergent field entering the skin and to have the convex shape of the contact device as shown, it is advantageous to use sapphire, the slightly higher index of which facilitates the desired field convergence.

**[0031]** With reference now to Fig. 3C, in order to conduct heat away from the epidermis, it is additionally preferred that the contact device 46 be composed of a material having a high thermal conductivity ( $k_{CD}$ ) which is similar to that of the skin. This allows efficient transfer of heat (indicated in the figure by the arrows 68) from the epidermis 56, across the contact device/epidermis interface 57, and into the contact device 46. A high thermal conductivity, in addition, is necessary to minimize local heating effects that may occur at the interface 57, thereby reducing the chance of thermally induced damage or injury to the irradiated epidermis. As will be discussed later, this is particularly important when the contact device is cooled. Ideally, the thermal properties of the contact device and the time the contact device is applied to the skin before irradiation begins allow minimization of heating near the epidermis, but have little effect on heat deposited near the papillae of the hair follicle (shown in the figure as region 70). Materials having high thermal conductivities include sapphire ( $K_{CD}=0.083 \text{ cal} \cdot \text{sec}^{-1} \text{ cm}^{-2} \text{ } ^\circ\text{Ccm}^{-1}$  along the C axis at  $30^\circ\text{C}$ ), fused silica ( $K_{CD}=0.026 \text{ cal} \cdot \text{sec}^{-1} \text{ cm}^{-2} \text{ } ^\circ\text{Ccm}^{-1}$  along the C axis at  $30^\circ\text{C}$ ), as well as other high-density glasses and plastics.

**[0032]** In addition, in order to improve both optical (i.e., transmission of back-scattered light) and thermal (i.e., heat conduction) properties at the contact device/epidermis interface 57, it is desirable to apply to the skin a topical liquid or emollient, such as a lotion, water, alcohol, or oil, having a refractive index which is similar to that of the contact device 46 and epidermis. For example, application of an oil having a refractive index between that of the epidermis ( $n=1.55$ ) and sapphire ( $n=1.7$ ) minimizes optical reflection effects at the interface, thereby allowing more efficient transfer of light into the skin region from the contact device and of back-scattered radiation from the skin region. Also, a liquid allows for more efficient transfer of heat by conduction from the skin into the sapphire, thereby reducing the

degree of damage or injury to the epidermis.

### Optical properties

**[0033]** The temporal and spatial distribution of intensity for the irradiating optical field inside the skin ultimately determine the amount of heat deposited into the target regions of the hair follicle; these properties therefore can be selected and/or adjusted to optimize the hair-removal process. In particular, properties which affect the hair-removal process include the pulse energy, pulse duration, repetition rate (i.e., the time duration between subsequent pulses), wavelength, energy, exposure spot size, beam convergence as it enters the skin, and mode geometry (i.e., spatial extent and uniformity) of the optical pulse. These characteristics may be selected according to the pigment present in the hair and skin to be irradiated; preferably, each parameter is adjusted so that the temperature at each target site, immediately following irradiation, is elevated to between about 80 and 120°C. Heating the follicle to this temperature leads to permanent damage and subsequent removal.

**[0034]** Referring now to Fig. 4, the wavelength of the irradiating field is chosen to be resonant with the natural pigment (i.e., melanin) present in the target sites (i.e., the hair shaft, bulge, matrix, and papilla). The absorption spectra of melanin, water, hemoglobin, and oxyhemoglobin shown in the figure indicate the ability of these compounds to absorb optical radiation at different wavelengths; low absorption indicates that light at the particular wavelength will penetrate deeper in the absorbing media. In general, in order to selectively heat the target regions, the wavelength of the irradiating field is chosen to match the absorption spectrum of melanin, which basically absorbs light from about 200nm, to 1200nm; conversely, the wavelength is mismatched to the absorption spectra of compounds contained in the skin, such as water and hemoglobin. Light having wavelengths between 680nm and 1200nm, a range indicated by the arrow 70 in the figure, is effectively absorbed by melanin while being relatively transmitted by both hemoglobin and water, and therefore can be used for selective heating of pigmented hair surrounded by white or lightly tanned skin. In particular, light in the range of 680nm to 900nm or 1000nm to 1200nm is preferred, as this radiation is strongly absorbed by melanin, and will not be absorbed by the bands present in water and in oxyhemoglobin near 950nm. For patients with less melanin present in the hair follicles (e.g. with auburn or light brown hair), the shorter wavelengths in this region are preferable because of the higher absorption coefficient of melanin. In addition, other light-attenuating effects besides absorption, e.g., scattering of radiation, are also wavelength-dependent, and should be considered during selection of the optical field's wavelength. For example, in human skin, the penetration of light is partially determined by the transport scattering coefficient ( $\mu_s$ ), which decreases at longer wavelengths due to scattering in the dermis. For radiation at 1000nm,  $\mu_s$  is about  $10\text{cm}^{-1}$ ; light propagating into the skin from a generally index-matched medium at this wavelength will therefore reach a maximum intensity at about 1mm below the skin surface.

**[0035]** Sources generating visible or near-infrared light in the preferred range of 680nm-1200nm include diode ( $\lambda=800\text{nm}-1000\text{nm}$ ), Nd:YAG and Nd:YLF ( $\lambda=1064\text{nm}$  and  $1053\text{nm}$ ), Ti:Sapphire and infra-red dye ( $\lambda=700\text{nm}-1000\text{nm}$ ), ruby ( $\lambda=694\text{nm}$ ) and alexandrite ( $\lambda=700\text{nm}-850\text{nm}$ ) lasers. Ruby, Nd:YAG and diode lasers (particular arrays of diode lasers) are preferred as these sources are commercially available, well-categorized, and can be manufactured on a small scale. Light sources of this type can be incorporated into compact hair-removal devices which, in turn, can be easily manipulated by the operator during hair-removal procedures.

**[0036]** The duration of the optical pulse can also be controlled in order to vary the heating of the hair follicle. Referring now to Fig. 5A, the optical pulses, indicated by the waveforms 74, 74', preferably have durations 76, 76' which allow the follicle to be heated for short periods of time. The pulse width is controlled to vary the heat conduction during the optical pulse, and thus the damage of the follicle and its immediate surrounding dermis; too little damage results in hair re-occurrence, while extensive damage may produce scarring in the irradiated region. Preferably, the pulse duration 76, 76' is between about 2ms and 100ms.

**[0037]** The exact pulse duration is dictated by the diffusion of heat in the skin, a process which roughly follows the heat diffusion equation relating the diffusion time  $t$ , diffusion distance  $d$ , and thermal diffusivity  $k$ , as discussed by in Welch, A.J. "The thermal response of laser-irradiated tissue", IEEE J. Quant. Electron. QE-21 (12), 1471-1481 (1984):  $t=d^2/4k$  ( $k$  for the human dermis is roughly  $1.3 \times 10^{-3}\text{cm}^2/\text{sec}$ ). The time needed for extraction of heat from the epidermis during a laser pulse is approximately 2ms, and the thermal relaxation time for a typical  $200\mu\text{m}$  hair follicle is approximately 40ms. For light exposures longer than a few hundred milliseconds, too much thermal diffusion may occur during the exposure period, resulting in either inefficient destruction of the target regions of the hair follicle, excessive dermal damage, or both. Further, since most of the melanin (roughly two thirds) in the epidermis is in the lower portion of the epidermis, heating of the epidermis occurs primarily in the deeper portions thereof, and some time is required for this heat to reach the surface in order to be removed by the contact device 46. Therefore, since this time is at least 2ms, this is the minimum suggested pulse duration, with a longer time, preferably at least 5ms, being suggested to minimize epidermal damage. Further, depending on the laser utilized, each pulse could be in the form of a single continuous pulse as shown in Fig. 5A or in the form of a train of closely spaced pulses of shorter duration, the space between such closely-spaced pulses being much shorter than 5ms.

**[0038]** For a given fluence, the intensity of the optical field is inversely related to the pulse duration; thus, when the pulse duration is below about 10 $\mu$ s, large optical intensities may result in undesirable modes of damage to surrounding skin regions. In addition, short pulses may result in localized heat-induced "explosions" in the follicle which cause mechanical damage to the skin. In particularly preferred embodiments, the pulse has a duration or pulsewidth of about 2ms-100ms. During this time period, thermal diffusion takes place over a distance of about 0.05mm to 0.3mm; damage confined to about this distance results primarily in destruction of the irradiated hair follicles, with little or no damage to the surrounding skin.

**[0039]** Optical pulses having well-defined and adjustable durations may be generated using known techniques. For instance, intra-cavity modulation of the light field using electro or acousto-optic Q-switching devices allows generation of pulses having temporal profiles which are typically Gaussian in shape. Pulses made using these methods are typically too short, however, having durations in the sub-microsecond range. Normal-mode pulses produced by flashlamp excitation of ruby, alexandrite, Ti:sapphire, or Nd:YAG lasers are preferred because these typically are high-energy pulses in the 0.1ms-10ms pulse duration region. Alternatively, a continuous (i.e., time-independent) optical field emitted by a laser can be externally modulated using, for example, a mechanical shutter or electro-optic gate. Modulation using external methods allows the pulse width to be easily varied from a few hundred microseconds to several hundred milliseconds. Pulses generated using external modulation may also have "square wave" temporal profiles (as shown in Fig. 5A) which allow a more uniform optical field to be applied to the region of interest. However, external modulation is not used for currently preferred embodiments.

**[0040]** When a contact device is used to deliver the optical pulse, a time delay preferably exists between the time at which the contact device contacts the skin surface and the arrival of the pulse. This allows the entire epidermal layer 56 to be cooled significantly prior to irradiation, thereby increasing its damage threshold. Pain and damage to the epidermis are thus reduced and are further minimized by continuing to cool contact device 46 during irradiation so that heat continues to be removed from the epidermis. However, heating at lower levels where destruction of the follicles, and in particular the bulge and papillae thereof, is desired is not affected by the cooling performed either before and/or during irradiation.

**[0041]** In addition, the time duration between optical pulses (indicated in Fig. 5A by the arrow 78) may be adjusted in order to control the total amount and rate on average of heat deposited into the irradiated region. If repetitive illumination is required for destruction of the follicle, this time period is preferably constant and lies between several seconds and a few hundred milliseconds. Alternatively, for "single shot" illumination, this time period is selectively controlled by the operator. In this case, a single laser shot is delivered to the region of interest, and then the region is inspected by the operator for damage. If more radiation is required, additional laser shots can then be delivered to the region. Otherwise, the irradiation unit is translated and used to treat a separate region.

**[0042]** The spatial extent of the optical field is chosen to allow multiple hair follicles to be irradiated with a single laser shot. In addition, larger spot sizes are preferred because attenuation along the beam axis within skin due to scattering decreases as the beam radius, R, increases. Thus, wide-area beams allow more efficient delivery of optical radiation to the deep target sites. Referring now to Fig. 5B, the width 80 of the spatial profile 82 of the irradiating beam at the surface of the skin is preferably on the order of, and preferably much greater than, the depth of the target to be irradiated. Most preferably, the beam diameter is at least 8mm. The area of the irradiating field is preferably between about 0.5cm<sup>2</sup> and 2cm<sup>2</sup>, and is most preferably between 0.75cm<sup>2</sup> and 1cm<sup>2</sup>. Because the beam is preferably converged, the spatial profile will be condensed as a function of depth before reaching a waist at a depth defined by optical scattering in the dermis. Preferably, as shown in Fig. 5B, the intensity across the beam diameter is roughly constant in order to provide a substantially uniform irradiating field.

**[0043]** Referring now to Fig. 6, following illumination, the intensity distribution of optical radiation (i.e., the y axis in the figure) as a function of skin depth (i.e., the x axis) is calculated using Monte Carlo-based computer simulations. The distribution is a function of the beam's spatial profile, the optical properties of the medium in contact with the skin. Although the plotted data is based on a computer simulation, and is thus only an approximate, the x axis units are estimated to be about 500  $\mu$ m per tick mark. The first curve 90 shows the skin depth-dependent properties of an optical field originating from a small, collimated spot of 800nm light in air. In this case, the majority of the optical intensity is distributed near the surface of the skin (indicated by the "0" point along the x axis), with the intensity dropping off rapidly at larger depths. A larger, collimated spot originating from air (curve 92) has a more evenly distributed skin depth-dependent intensity, although the majority of the light is still concentrated near the skin surface. Delivering a large, collimated radiation spot from a material having a refractive index of 1.5 (curve 94) results in a relatively uniform optical intensity in the first millimeter or so of the skin; at larger depths, this intensity starts to tail off with a relatively slow time constant. Finally, in the preferred embodiment, a large, spatially converging optical field from the n=1.5 refracting material has an intensity at the skin surface which increases to a maximum after propagating about a millimeter into the skin. The intensity then attenuates as a function of skin depth with a time constant slower than that exhibited by the curve 94. Thus, a field of this type can be used to effectively heat the target sites of the follicle, with reduced heating of the skin at the surface, thus reducing heat injury to the skin.



[0044] In the case where the illuminating laser generates a beam having a diameter less than the preferred values, it may be necessary to expand the beam prior to delivery to the irradiating unit. This may be done with conventional telescoping optics, e.g., two-lens systems configured to first expand and then collimate the emitted beam. Alternatively, as shown in Fig. 2A, the irradiating field may be coupled into an optical fiber and then delivered to the irradiating unit. In this case, the emerging field is naturally dispersed due to the waveguide nature of the fiber, and is then collected by a collimating lens. Displacement of the lens from the fiber tip allows the irradiating beam's profile to be increased to the desired amount.

[0045] The fluence of the optical field will be varied according to the degree of pigmentation in the patient, and is preferably between about 10J/cm<sup>2</sup> and 200J/cm<sup>2</sup> for each pulse; patients with darker hair will require lower fluence than patients with lighter hair. Most preferably, the pulse fluence of the irradiating field for pulses of about 1ms duration is between 30J/cm<sup>2</sup> and 50J/cm<sup>2</sup>. As described herein, in all cases, the fluence is adjusted in order to heat the target regions to the desired temperature of approximately 80°C to 120°C. Moreover, the level of fluence may be increased as the pulse duration is increased in order to compensate for less efficient heating of follicles due to heat conduction during long pulses. It may be necessary to increase or decrease the optical fluence in order to heat the hair follicle to the desired temperature if the wavelength of the irradiating light field does not lie in the preferred spectral regions (i. e., 680nm-900nm or 1000nm-1200nm). In addition, in cases where the laser output is below the desired optical fluence, it may be necessary to amplify the individual pulses prior to irradiating the skin. Optical amplifiers, such as external optical cavities, may be used for this purpose.

[0046] Table 1, shown below, lists the preferred parameters of the optical fields used for hair removal. The value of each parameter depends on the amount of hair in the region of interest, the degree of pigmentation of the hairs, and the pigmentation of the surrounding skin of the patient.

Table 1 -

Preferred Optical Field Parameters		
parameter	range	preferred values
wavelength	680nm-1200nm	680nm-900nm, 1000-1200nm
pulse duration	50μs - 200ms	2ms-100ms
beam area	>0.5cm <sup>2</sup>	0.7cm <sup>2</sup> -1.0 cm <sup>2</sup>
pulse energy	10J/cm <sup>2</sup> -200J/cm <sup>2</sup>	30 - 50 J/cm <sup>2</sup>
optical coupling	external n≥1.4	n=1.5 to 1.7
beam convergence, at skin surface	collimated or convergent	f#0.5-2

[0047] The invention will now be further described with reference to the following examples.

#### Examples

[0048] In order to demonstrate the efficacy of a hair-removal device according to the invention, in vitro black-haired dog skin was exposed to light from the normal mode of a ruby laser at  $\lambda=694\text{nm}$  with a pulse duration of 270μs and optical fluences of 40J/cm<sup>2</sup>, 71J/cm<sup>2</sup>, and 160J/cm<sup>2</sup>.

[0049] The spatial extent of the beam (8mm diameter at the skin surface) allowed irradiation of approximately 100 hairs with a single laser shot. Following irradiation, each skin region was examined histologically. Examination revealed that at the highest fluences, dermal damage consistent with scarring of the skin was evident, indicating that at the highest fluences, light-induced thermal damage was not selective to the hairs. In contrast, at the lower fluences, and particularly at 40J/cm<sup>2</sup>, localized follicular damage was observed, with no noticeable damage occurring in the neighboring skin regions or dermis between hair follicles.

[0050] In a separate set of experiments, in order to show that the temperature increase within the irradiated hair is dependent on the degree of pigmentation, fresh human hair and skin samples having different colors were exposed using the hair-removal method described herein. The light source for all experiments was the ruby laser described above. Emitted light was first coupled into an enclosed beam-steering device containing several mirrors coated to have high reflectivities at 694nm, and then delivered to an irradiating unit similar to that shown in Fig. 2B. The unit included a 5-cm plano-convex glass lens positioned at the proximal end of a water-cooled plexiglass housing. A sapphire contact device shaped as a 1-cm focal length lens was disposed at the distal end of the contact device, with the convex side touching the skin to allow compression during exposure as described above. Human skin was irradiated with an 8mm

diameter beam by pressing the cooled (4°C) contact device against the skin region of the patients, and then delivering a single laser shot. Each shot typically resulted in the simultaneous exposure of about 10 hairs.

**[0051]** The skin and hair of six adult patients having hair color ranging from red to black was irradiated and then observed. In each patient, eight treatment sites, each having an area of 10cm<sup>2</sup>, were irradiated. In order to monitor destruction of the papilla, sites 1-4 were wax-epilated prior to exposure to laser light, while sites 5-8 were shaven prior to exposure. Each site then received an optical fluence of either 28J/cm<sup>2</sup>, 42J/cm<sup>2</sup>, or 57J/cm<sup>2</sup>. Patients were seen in follow-up examinations one month and three months (and for some patients also one year) after exposure. As seen from the photographs of the exposed regions shown in Fig. 7 (i.e., regions A-C), hair regrowth after three months was minimal or non-existing in all cases compared to the shaved-but-untreated region (Region D), clearly indicating permanent damage to the hair follicle. In the figure, sites A-C were treated with decreasing energy from the laser. It is clearly evident that hair removal is relatively less pronounced in region C, treated with a fluence of 27J/cm<sup>2</sup>. Region D, the control region, was shaven at the same day regions A-C were treated. In addition, histological specimens obtained from the treated sites revealed that damage occurred exclusively to the hair follicle, while the surrounding dermis was essentially spared. There was statistically significant loss of hair for all of the subjects in the laser-treated sites compared with unexposed, shaven control sites. At one year later, there was also significant permanent hair loss without any scarring.

**[0052]** A separate set of experiments permitting measurement of the time-dependent temperature characteristics of hair and skin samples were conducted using a pulsed photothermal radiometry (PPTR) apparatus. In these experiments, the ruby laser described above was used at lower fluences to provide optical pulses having an energy allowing heating, but not destruction, of the follicles. Output from the laser was focussed onto the samples of human hair and skin to provide a uniform excitation field. A New England Research, Inc. black-body radiation detector containing an amplified, liquid nitrogen-cooled HgCdTe detector was used to monitor time-dependent characteristics of the sample temperature, and a Gentec, Inc. laser energy meter was used to monitor the irradiating pulse. The output from both detectors was then amplified with a compensated 0-10Mhz dc-coupled preamplifier, and then relayed to a digital oscilloscope for recording and storing the data.

**[0053]** Eight patients having various skin types and hair coloring ranging from red/blonde to black were studied. In general, the PPTR results indicated that following irradiation at 694nm, black hair experienced a larger temperature rise than lighter brown hair, and that both of these specimens experienced higher temperature rises compared to red/blonde hair. In addition, following irradiation, type II skin had a lower temperature rise than type III or type IV skin.

**[0054]** Referring now to Figs. 8A-8C, in a particular example using a patient with black hair and white skin, time-dependent traces measured using the PPTR apparatus indicate that 400ms after irradiation, both wet and dry black hair experience, respectively, temperature rises of about 7°C and 72°C (Figs. 8A and 8B) from a baseline temperature of 23°C, whereas the surrounding skin (Fig. 8C) undergoes a temperature rise of less than 1°C. The difference in the temperature rise and time-dependent decay characteristics of the wet hair is likely due thermal effects (e.g., the higher heat capacity of wet hair).

**[0055]** Referring now to Fig. 9, in all cases, the normalized temperature rises (i.e, the ratio of temperature rise to laser pulse energy) in the wet and dry hair follicles were significantly higher than those measured in the skin, indicating selective heating of the follicles. Table 2, shown below, lists the hair and skin types of each patient in the study. The patient numbers in the table correspond to the patient numbers in Fig. 9.

Table 2 -

Patient Hair and Skin Types		
patient	hair	skin type
1	red	II
2	brown	III
3	brown	II
4	gray/black	III
5	gray/Black	III
6	dark brown	III
7	gray/black	II
8	black	III

## Other Embodiments

**[0056]** Fig. 10A illustrates an alternative embodiment of the invention wherein the region 20 is epilated rather than being merely shaved prior to treatment. A fluid solution or suspension 100 containing a chromophore may then be applied to the skin region 20, with the chromophore containing fluid migrating into the empty follicles and filling the follicles. "Capillary action" of the fluid/chromophore into the follicles is desirable and may be enhanced by providing a low surface tension between the fluid and skin, for example by using surfactants or solvents. The excess fluid/chromophore may then be removed from the skin surface by washing, wiping or stripping. During irradiation, the chromophore 100 in the follicle absorbs light and is heated and, along with the heating of the melanin of the follicle itself, results in significant heating of the follicle to destroy the portions thereof, including the bulge and the papilla, required to prevent regrowth of hair. The chromophore therefore must absorb light at the wavelength or wavelengths used for irradiation. Suitable chromophores might include a carbon particle suspension or a dye such as methylene blue or indocyanine green. Melanin itself in liposomal form might also be used. Since the chromophore is only in the follicles, this technique maximizes damage to the follicles while minimizing damage to surrounding tissue, and for this reason is a preferred way of practising the invention, especially for those with blond, red, light brown or other light colored hair. Except for the differences indicated above, this embodiment of the invention operates in the same manner described for earlier embodiments, including the cooling of contact device 46, the deformation of the skin in the region 20, and the preferred optical irradiation, with the exception that lower frequency may be allowed when using the chromophores.

**[0057]** Fig. 10B illustrates another alternative embodiment of the invention wherein the contact device or applicator 46' is modified so as to simultaneously expose both sides of a skin fold. This further increases the relative delivery of light to the deep portion of the follicles. In Fig. 10B, the contact device has for example an opening or slot 110 in the face of the applicator into which the area 20 of the skin may be drawn by for example vacuum or suction being applied to line 112 leading into the top of slot 110, the skin in slot 110 being formed into a fold 113. Radiation may be applied through a fiber-optic bundle 114 which divides to apply the radiation to lenses 116 on either side of slot 110. Cooling water may be flowed over the surfaces of lenses 116 through a line 118. Alternatively, two applicators similar to those shown for example in Fig. 2A or 2B can be positioned on opposite sides of a skin fold formed by clamping the skin region therebetween or by other suitable means.

**[0058]** The advantage of folding the skin as discussed for the above embodiments is that radiation is applied to a relatively thin section of skin from both sides. Thus, the papilla of a given follicle may be receiving radiation not only from the lens 116 on the side of slot 110 where the follicle is located, but also some radiation from the lens 116 on the opposite sides of the slot. Thus, energy applied to the papilla of each follicle is increased without increasing the energy at the surface, thus facilitating hair removal with less pain and injury. By making the slot 110 relatively narrow, pressure is applied to the skin on both sides of the slot, the skin being compressed between the walls of the slot. The advantages of compressing the skin, including removing blood therefrom and reducing the distance from the skin surface to the papilla, are thus also achieved by this embodiment of the invention. Clamping to form the fold would also apply pressure to the skin.

**[0059]** It may also be possible to utilize the apparatus of this invention for short term hair removal, the device serving as for example a razor which might provide a shave lasting for perhaps one to two weeks. This is achieved by applying the fluid/chromophore to the region which is to be "shaved" which region has preferably been shaved using conventional techniques, but not epilated. In this case the chromophore can only migrate a few millimeters into the follicle, to for example the level of the sebaceous gland. Excess chromophore may then be removed, and the contact device of this invention utilized with relatively low level radiation to heat the chromophore, and destroy the hair surrounded thereby, without substantial damage to either the skin or follicle.

**[0060]** Further, while cooling water has been shown for the preferred embodiment to cool contact device 46, this is not a limitation on the invention and other cooling techniques may be utilized. For example, a low temperature gas or liquid gas may be passed over the contact device for cooling purposes or the contact device may be sufficiently cooled prior to use so that it can continue to perform the cooling function during irradiation without having a cooling medium passed thereover. Other cooling techniques known in the art may also be utilized.

**[0061]** Other embodiments are within the scope of the following claims. For example, the contact device may not be cooled or cooling of the epidermis may be performed without an applicator (for example cryogenically). Where an applicator is not utilized, radiation is applied directly to the region of interest after passing through the appropriate optics.

## Claims

1. Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46');  
a source (12) of optical radiation; and  
an optical path (16) (114) from the source of optical radiation to the said surface of the said applicator, which  
path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed  
through the said surface of the said applicator to the said skin region,

**characterised in that** the said radiation has a wavelength between 680nm and 1200nm and a fluence of  
between 10J/cm<sup>2</sup> and 200J/cm<sup>2</sup>, and **in that** the duration of the radiation on the said skin region is 50µs to 200ms.

**2.** Apparatus according to claim 1 in which the duration of the radiation on the said skin region is 5ms to 200ms.

**3.** Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle  
extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46');  
a source (12) of optical radiation; and  
an optical path (16) (114) from the source of optical radiation to a surface of the said applicator, which path is  
substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed  
through the said surface of the said applicator to the said skin region,

**characterised in that** the apparatus further comprises means (50, 52) (118) for cooling a surface of the  
applicator to a temperature below that of the said skin region.

**4.** Apparatus according to claim 3 wherein the said cooling means (50, 52) (118) cools the said surface of the  
applicator (18) (46') below that of the said skin region by an amount which is sufficient in conjunction with selected  
radiation to prevent substantial heating of the said skin region with which the applicator is in contact for a selected  
depth and not to substantially interfere with heating of the skin in the said region beyond the said selected depth.

**5.** Apparatus according to claim 3 or 4 wherein the means for cooling (50, 52) (118) is a channel near the said  
surface of the applicator (18) (46') through which cooling water is passed.

**6.** Apparatus according to claim 1, 3, 4 or 5 wherein the said radiation has a wavelength between 680nm and  
1200nm, preferably between 680nm and 900nm, and a fluence of between 10J/cm<sup>2</sup> and 200J/cm<sup>2</sup>, and in that the  
duration of the radiation on the said skin region is 2ms to 200ms.

**7.** Apparatus according to any preceding claim wherein at least the said surface of the applicator (18) (46') is  
formed of a material having a refractive index which substantially matches the refractive index of the skin surface  
in the said skin region.

**8.** Apparatus according to any preceding claim in which the applicator (18) (46') comprises a surface adapted to  
be in contact with the skin surface in a skin region from which hair is to be removed.

**9.** Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle  
extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46') comprising a surface adapted to be in contact with the skin surface in a skin region  
from which hair is to be removed;  
a source (12) of optical radiation; and  
an optical path (16) (114) from the source of optical radiation to the said surface of the said applicator, which  
path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed  
through the said surface of the said applicator to the said skin region,

**characterised in that** at least the said surface of the applicator (18) (46') is formed of a material having a  
refractive index which substantially matches the refractive index of the skin surface in the said skin region.

**10.** Apparatus according to any preceding claim further comprising an element (42, 46) (116) in the optical path  
for converging the optical radiation as it leaves the applicator (18) (46') through the said surface.

**11.** Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46') comprising a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed;  
a source (12) of optical radiation; and  
an optical path (16) (114) from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region,

**characterised in that** further comprising an element (42, 46) (116) in the optical path for converging the optical radiation as it leaves the applicator (18) (46') through the said surface.

**12.** Apparatus according to claim 10 or 11 wherein the said element (42, 46) (116) is a lens.

**13.** Apparatus according to any of claims 9 to 12 wherein the said radiation has a wavelength between 680nm and 1200nm, preferably between 680nm and 900nm, and a fluence of between 10J/cm<sup>2</sup> and 200 J/cm<sup>2</sup>, and in that the duration of the radiation on the said skin region is 2ms to 200ms.

**14.** Apparatus according to any preceding claim wherein the applicator (18) (46') further comprises a housing (48), the said surface being disposed on the housing and having a convex shape and the said optical path (16) (114) passing through the said housing from the source (12) of optical radiation to the said surface.

**15.** Apparatus according to any preceding claim wherein the said surface of the applicator (46') has a slot (110) formed therein and wherein the optical path (114) leads to at least two opposite sides of the slot and includes means (112) for positioning at least a portion (113) of the said skin region into the slot.

**16.** Apparatus according to claim 15 wherein the means for positioning includes means (112) for applying vacuum to the slot.

**17.** Apparatus according to any preceding claim wherein the source (12) of optical radiation is a laser.

**18.** An applicator suitable for use in practising a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin, from a skin surface, comprising:

a housing;  
a transmitter of optical radiation into said housing;  
a surface disposed on the housing having a convex shape and adapted to be in pressure contact with the skin surface in the said skin region;  
an optical path through said housing from the transmitter of optical radiation to the said surface which path is substantially transparent to optical radiation at the said selected wavelength;  
an element in the optical path for converging the optical radiation as it leaves the applicator through the said surface; and  
means for cooling the said surface to a temperature below that of the said skin region.

**19.** An applicator according to claim 18 in which: the said surface disposed on the housing shaped to contact the skin surface in the said skin region has a slot formed therein; and in which the optical path leads to at least two opposite sides of the slot, and includes means for positioning at least a portion of the said skin region into the slot.

**20.** An applicator as claimed in claim 19 wherein the means for positioning includes means for applying vacuum to the slot.

**21.** An applicator according to claim 18, 19 or 20 wherein at least the said surface is formed of a material having a refractive index which substantially matches the refractive index of the skin surface in the said skin region.

**22.** An applicator according to any of claims 18 to 21 wherein the element is a lens.

**23.** An applicator according to any of claims 18 to 21 wherein the means for cooling is a channel near the said

surface through which cooling water is passed.

**24.** Apparatus for the simultaneous removal of a plurality of hairs from a skin region containing the plurality of hairs, each hair being in a follicle extending into the skin from a skin surface, the apparatus comprising:

an applicator which is adapted to be in pressure contact with a portion of the skin surface containing a plurality of hairs in the said skin region, the applicator having a surface in contact with the skin surface, and including a mechanism which cools the said surface of the applicator below that of the said skin region by an amount which is sufficient in conjunction with selected radiation to prevent substantial heating of the said skin region in which the applicator is in pressure contact for a selected depth and not to substantially interfere with heating of the skin in the said region beyond the said selected depth;  
a source of optical radiation; and  
means for applying the optical radiation from the source to the applicator, the optical radiation being passed through the applicator to the said skin region.

**25.** Apparatus according to claim 24 wherein the radiation from the source of optical radiation is of a wavelength between 680nm and 1200nm, a fluence between 10J/cm<sup>2</sup> and 200J/cm<sup>2</sup> and a pulse duration between 50µs and 200ms.

**26.** Apparatus according to claim 25 wherein the means for cooling includes a channel near the said surface through which cooling water is passed.

**28.** Apparatus according to any of claims 24 to 26 wherein the applicator has a surface in contact with the skin surface, the said surface of the applicator having a slot formed therein, wherein the means for applying the optical radiation includes optical paths in the applicator leading to at least two opposite sides of the slot, and wherein the applicator includes means for positioning at least a portion of the said skin region in the slot between the said at least two opposite sides.

**29.** Apparatus according to any of claims 1 or 3 to 28 wherein the duration of the radiation on the said skin region is 2ms to 100ms.

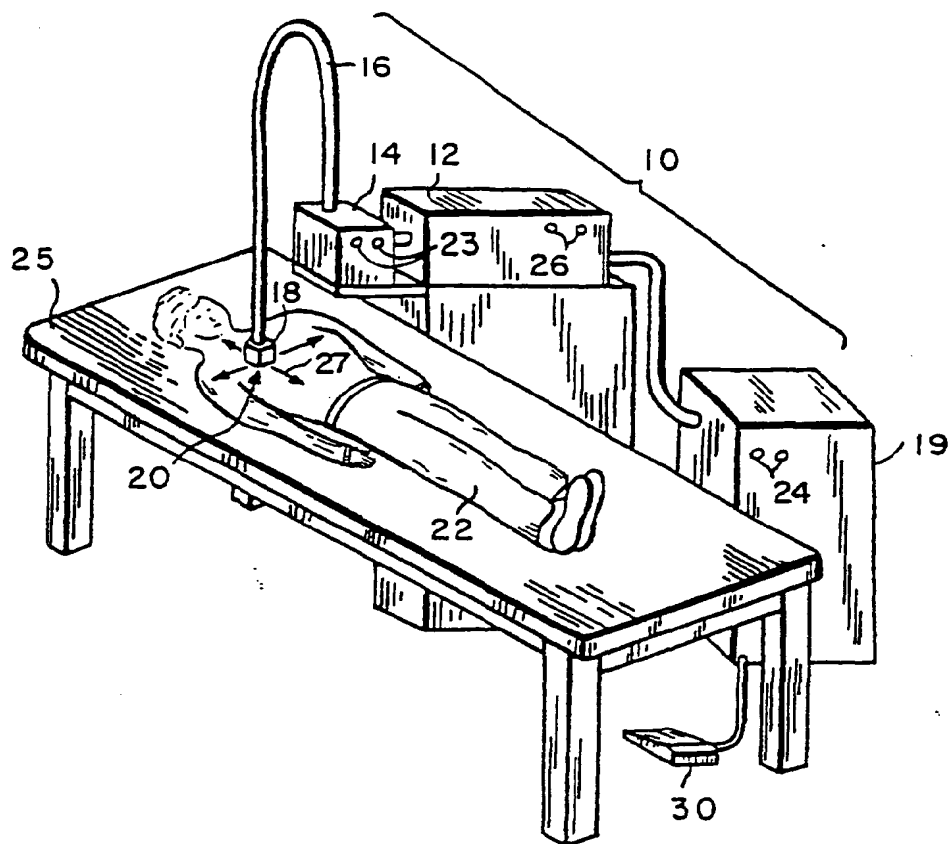


FIG. 1

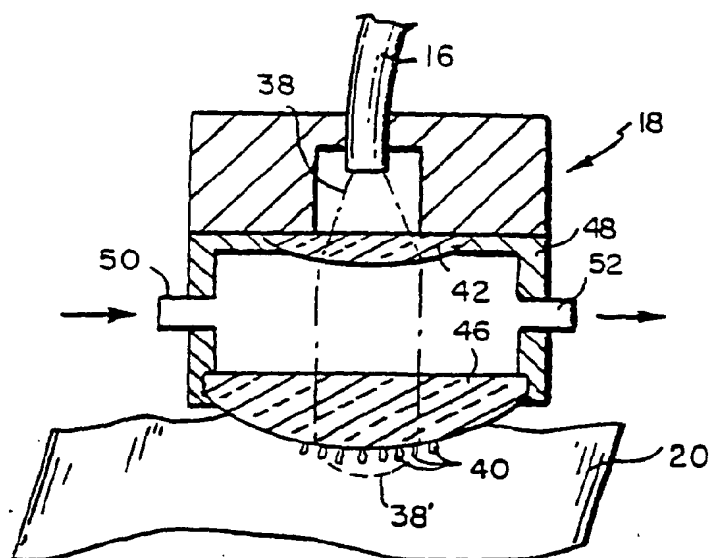


FIG. 2A

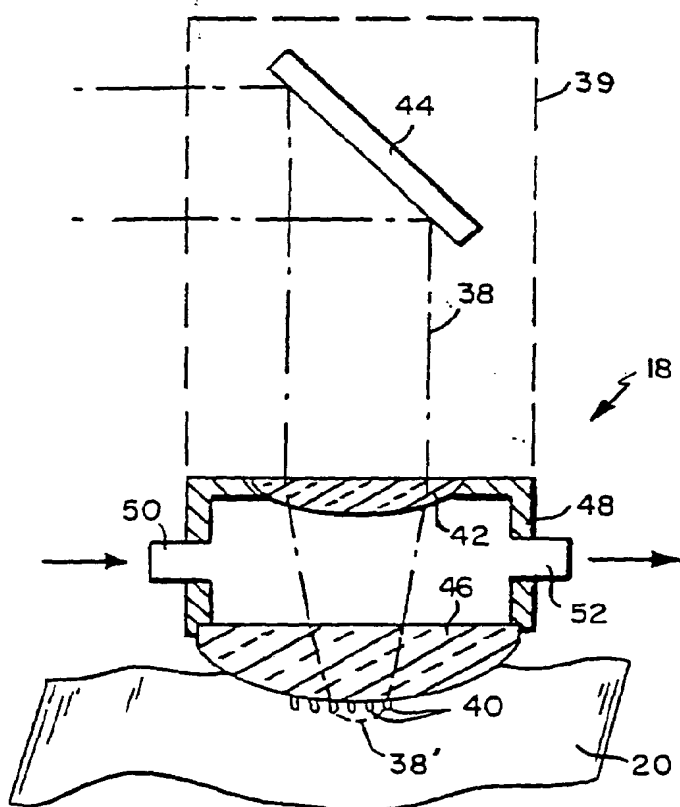


FIG. 2B



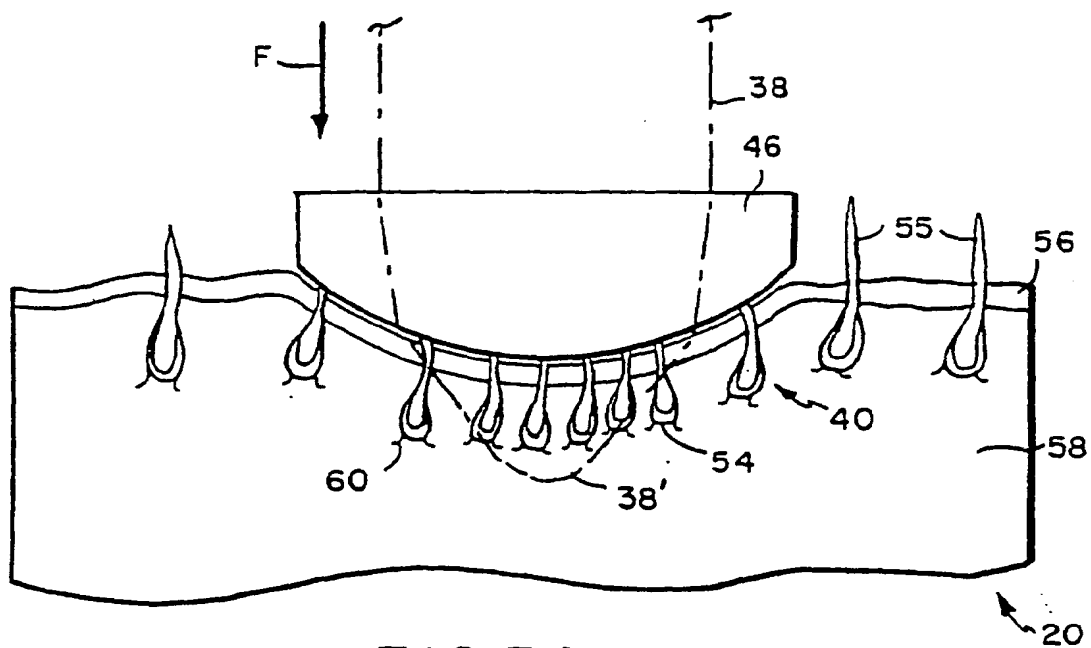


FIG. 3A

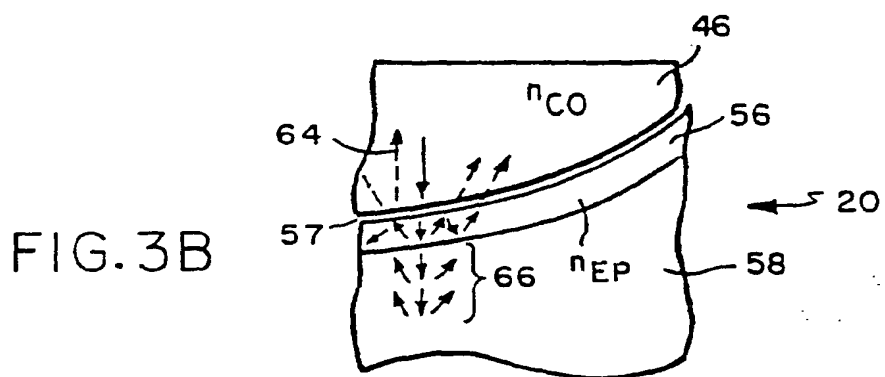


FIG. 3B

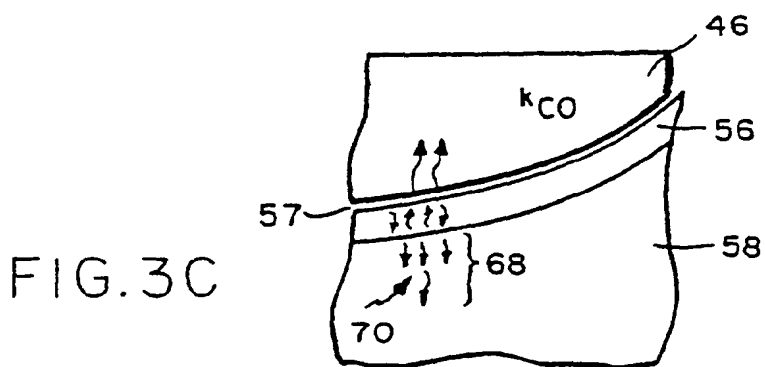


FIG. 3C

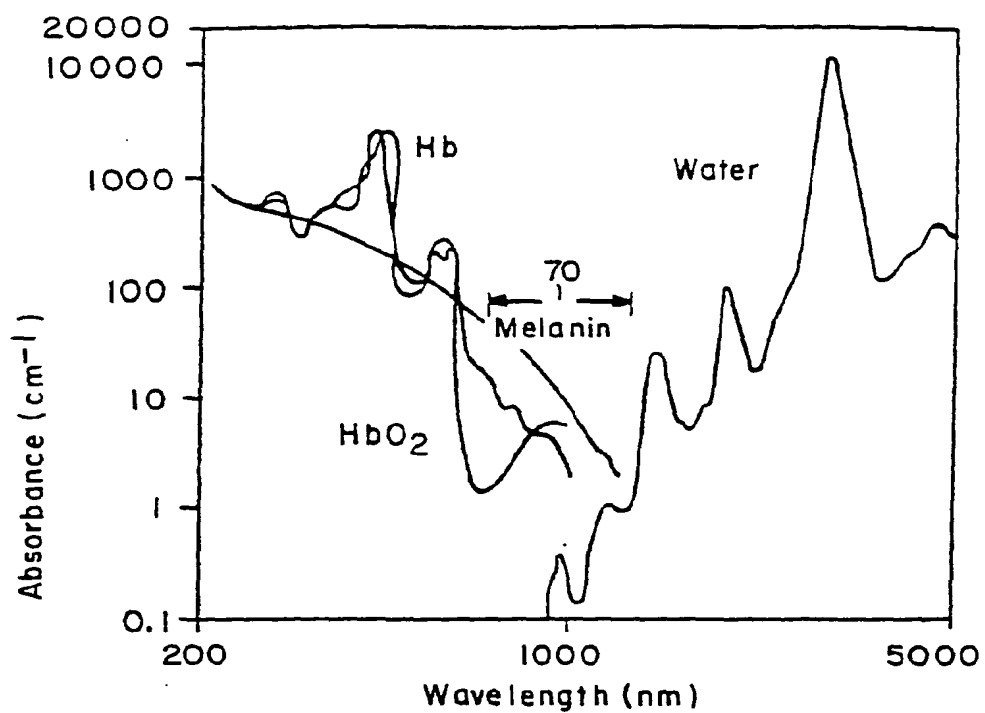


FIG. 4

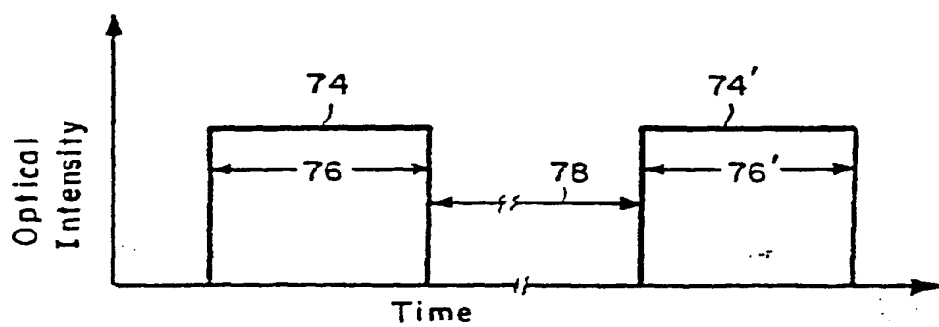


FIG. 5A

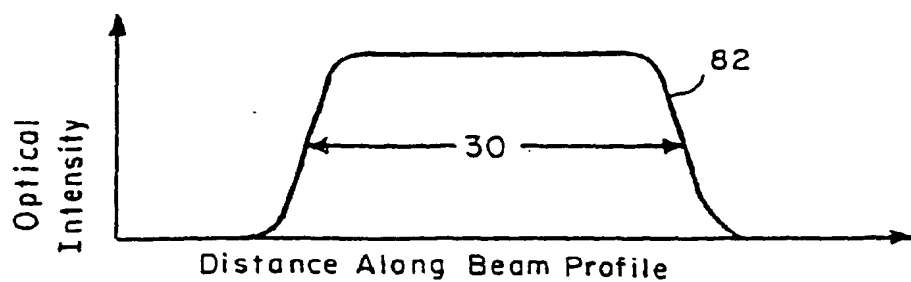


FIG. 5B

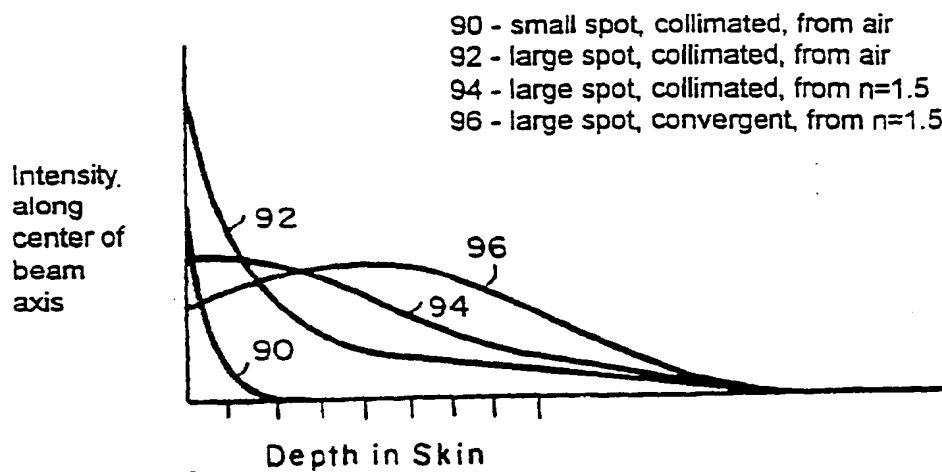


FIG. 6

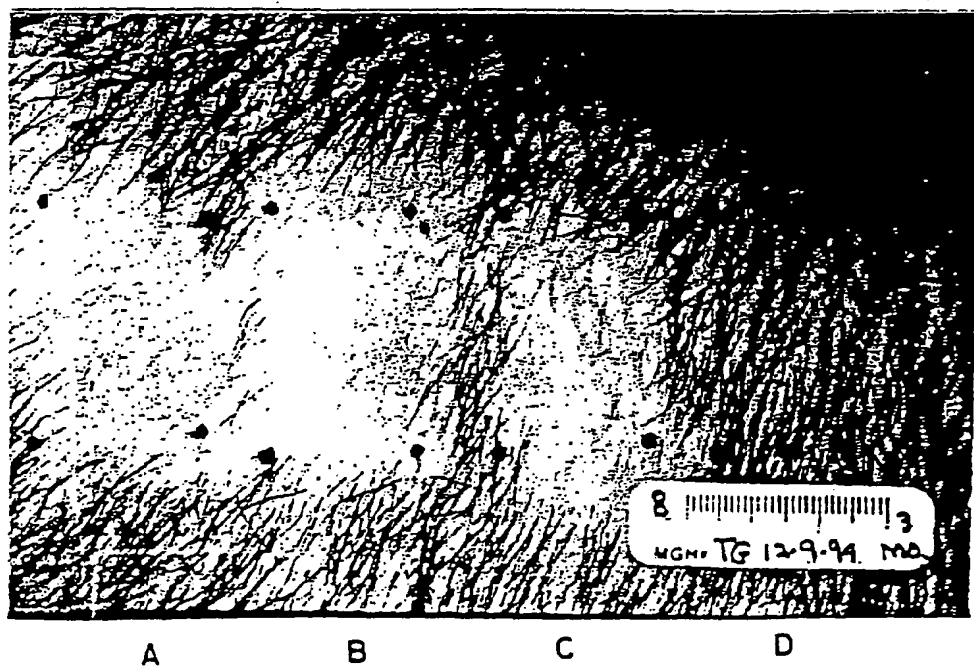


FIG. 7

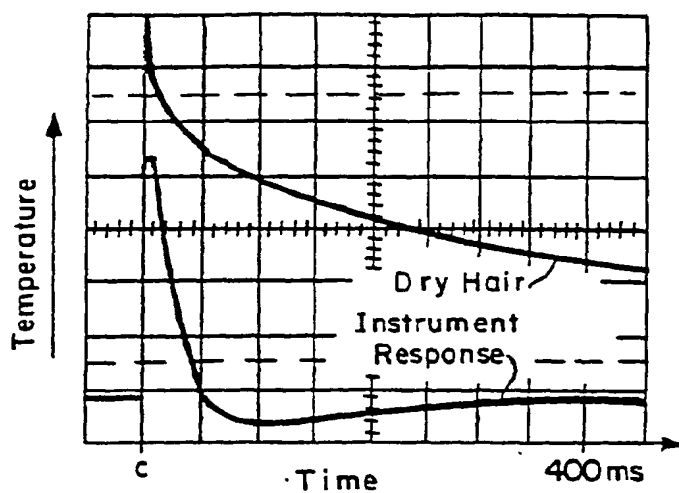


FIG. 8A  
(Dry Hair)

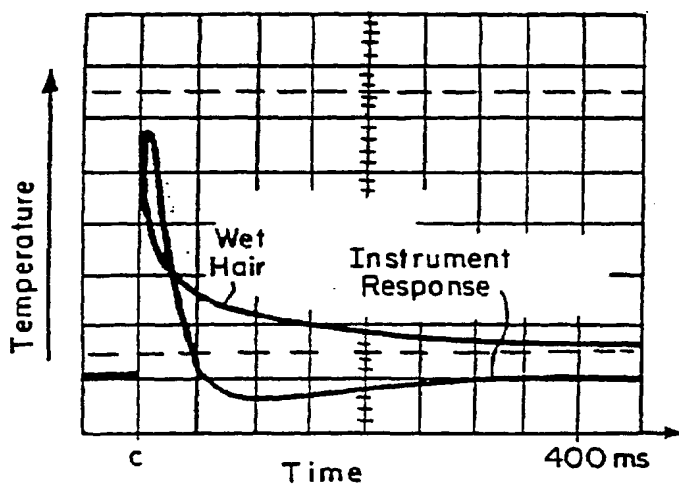


FIG. 8B  
(Wet Hair)

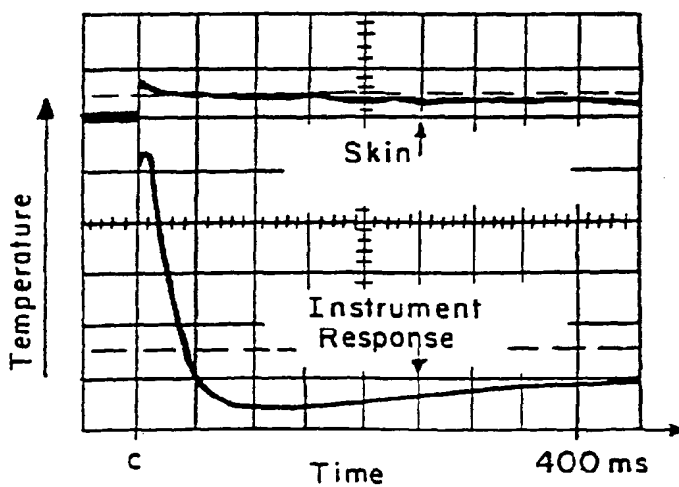


FIG. 8C  
(Skin)

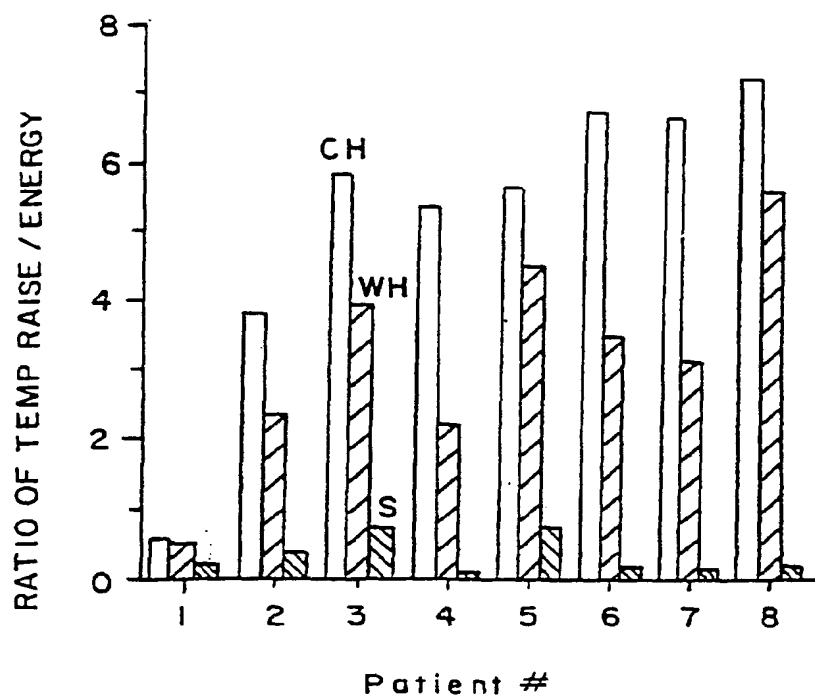


FIG. 9

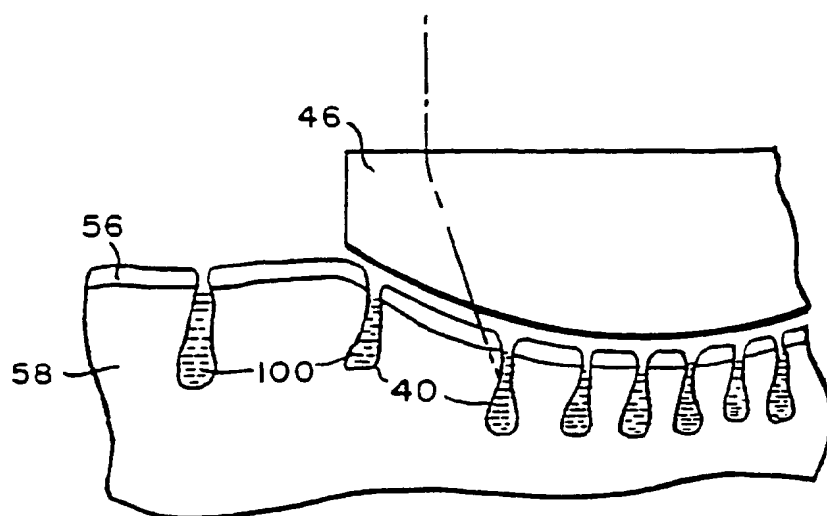


FIG. 10A

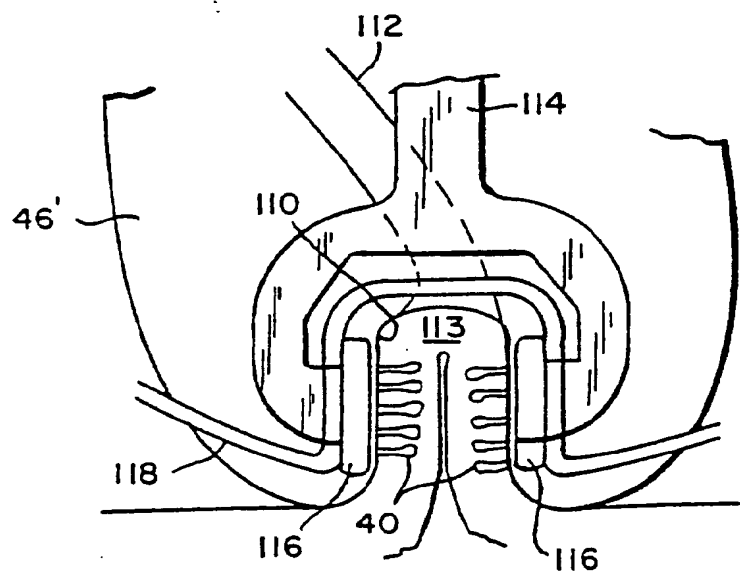


FIG. 10B



European Patent  
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# EUROPEAN SEARCH REPORT

Application Number  
EP 04 07 7257

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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-/--			
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 16 November 2004	Examiner Mayer-Martenson, E
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons  &amp; : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03/02 (P04/01)



European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number  
EP 04 07 7257

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 16 November 2004	Examiner Mayer-Martenson, E
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons  &amp; : member of the same patent family, corresponding document</p>			

EPO FORM 1503 (03.92) (P04C01)





European Patent  
Office

Application Number  
EP 04 07 7257

### CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

### LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☒ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



European Patent  
Office

**LACK OF UNITY OF INVENTION  
SHEET B**

Application Number  
EP 04 07 7257

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1,2,6-8,10,14,15,16,17,29

laser for epilation with a wavelength of 680nm-1200nm  
---

2. claims: 3-5,18-28

laser for epilation with cooled surface  
---

3. claim: 9

laser for epilation with surface matching the refractive  
index of skin  
---

4. claims: 11-13

laser for epilation with element for converging optical  
radiation  
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**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 07 7257

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
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16-11-2004

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**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 07 7257

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(54) **Method for assessing pigmented skin**

(57) The present invention features a method of approximating the relative contribution of melanin and/or deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin.

**Description****FIELD OF INVENTION**

5 [0001] The present invention relates to the assessment of pigmented skin.

**BACKGROUND OF THE INVENTION**

10 [0002] The chromatic characteristics of skin color arise from the interactions of light (primarily absorption and scattering) with the epidermis and the dermis. The primary light absorbers in skin are hemoglobin and melanin. Most of scattering is attributed to collagen fibers and in pigmented skin to melanosomes. Traditionally, skin redness is considered to arise due to locally elevated concentrations of hemoglobin, whereas skin pigmentation is attributed to melanin.

15 [0003] Human skin is structurally and optically heterogeneous. It consists of two discrete layers, the epidermis and the dermis, each with different biological structure and different optical properties arising from their individual absorbing and scattering constituents. The epidermis is a highly cellular tissue consisting of layers of keratinocytes. It is known that the primary absorber in the epidermis is melanin. It has also been shown (Kollias, et al., (1991) J Photochem Photobiol B 9(2): 135-160) that particulate melanin is a major contributor to epidermal scattering. Melanin is synthesized in specialized organelles, the melanosomes, which are manufactured in the melanocytes that are found at the basal layer of the epidermis. The melanosomes are secreted from the dendritic processes of the melanocytes, and they are phagocytosed by the keratinocytes.

20 [0004] The dermis is essentially an acellular tissue sparsely populated by fibroblasts. It consists primarily of extracellular matrix components (collagen and elastin), blood vessels, and lymphatic vessels. Collagen microfibrils are organized into fibers and the fibers into bundles. These structures constitute the major cause of light scattering in the skin. Hemoglobin is found in the dermal blood supply and is responsible for the red appearance of skin, as in the case of erythema. Skin hemoglobin is confined in networks of arterial and venous plexi that run approximately parallel to the skin surface and in small capillaries that run vertical to the skin surface and reach close to the dermal-epidermal junction in the form of capillary loops. Anatomically, one can distinguish a superficial arterial and venous plexus and a deeper plexus. The capillaries stem from the superficial arterial plexus and empty in the superficial venous plexus. The superficial and deeper plexi are interconnected through smaller vessels. At the deeper level, arteriovenous anastomoses (shunts) provide ways for blood flow to bypass superficial skin layers, thus enabling skin thermal regulation. Circulating erythrocytes in the blood vessels contain high concentrations of hemoglobin. The hemoglobin molecule has four heme groups, which can bind to and deliver oxygen molecules to the tissues. When these binding sites are unoccupied, the molecule is called deoxy-hemoglobin (deoxy-Hb) or reduced hemoglobin. When oxygen molecules occupy these binding sites, it is termed oxy-hemoglobin (oxy-Hb) or oxygenated hemoglobin. Each form of hemoglobin has its own characteristic absorption profile (Kollias, (1995) Clin Dermatol 13(4):361-367).

35 [0005] It follows from the above that the visual perception of skin color is the cumulative result of contributions of various optically active molecules that are found in varying concentrations in the skin. The relative contributions of each chromophore can be evaluated quantitatively by analyzing the remittance spectra of skin tissue. Applicants have discovered that deoxy-hemoglobin not only contributes to erythema, but also surprisingly contributes to perceived pigmentation of the skin. Applicants have accordingly modified the analysis of remittance spectra to take into account this discovery.

**SUMMARY OF THE INVENTION**

45 [0006] In one aspect, the present invention features a method of approximating the relative contribution of melanin responsible for the perceived pigmentation of an area of skin including the steps of (i) determining the absorbance of light at a wavelength of from about 620 nm to about 750 nm at such area of skin and (ii) subtracting the approximate relative contribution of deoxy-hemoglobin from such absorbance.

50 [0007] In another aspect, the present invention features A method of approximating the relative contribution of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin including the steps of (i) determining the absorbance of light at a wavelength of from about 550 nm to about 590 nm at such area of skin and (ii) subtracting the approximate relative contribution of oxy-hemoglobin and melanin from such absorbance.

55 [0008] In another aspect, the present invention features a method of approximating the relative amount of melanin responsible for the perceived pigmentation of an area of skin, including the steps of: (i) measuring the reflectance of a first light at a wavelength of from about 555 nm to about 565 nm, a second light at a wavelength of from about 570 nm to about 585 nm, a third light at a wavelength of from about 620 nm to about 650 nm, and a fourth light at a wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of the third light and the fourth

light at such area of skin; (iii) subtracting the first approximate relative contribution of melanin from the determined absorbance of the first light and the second light at such area of skin; (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of the first light and the second light of step (iii); and (v) subtracting the first approximate relative contribution of deoxy-hemoglobin from the first approximate relative contribution of melanin to obtain a final approximate relative contribution of melanin.

**[0009]** In another aspect, the present invention features a method of approximating the relative amount of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin including the steps of: (i) measuring the reflectance of a first light at a wavelength of from about 555 nm to about 565 nm, a second light at a wavelength of from about 570 nm to about 585 nm, a third light at a wavelength of from about 620 nm to about 650 nm, and a fourth light at a wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of the third light and the fourth light at such area of skin; (iii) subtracting the first approximate relative contribution of melanin from the determined absorbance of the first light and the second light at such area of skin; and (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of the first light and the second light of step (iii).

**[0010]** In another aspect, the present invention features a method of approximating the relative contribution of melanin to a perceived pigmentation of an area of skin including the steps of: (i) examining such skin with a device including a light source and a reflectance detector, wherein the detector measures the reflectance from such area of skin of light generated by the light source of at a first wavelength of from about 555 nm to about 565 nm, at a second light wavelength of from about 570 nm to about 585 nm, at a third wavelength of from about 620 nm to about 650 nm, and at a fourth wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the first approximate relative contribution of melanin, to such perceived pigmentation by using the calculated absorbance of the third wavelength and the fourth wavelength at such area of skin; and (iii) further determining the approximate relative contribution of melanin by subtracting from the first approximate relative contribution of melanin the approximate relative contribution of deoxy-hemoglobin determined by the absorbance of the first wavelength and the second wavelength at such area of skin.

**[0011]** In another aspect, the present invention features a method of approximating the relative contribution of deoxy-hemoglobin to a perceived pigmentation of an area of skin including the steps of: (i) examining such area of skin with a device including a light source and a reflectance detector, wherein the detector measures the reflectance from such area of skin of light generated by the light source of at a first wavelength of from about 555 nm to about 565 nm, at a second light wavelength of from about 570 nm to about 585 nm, at a third wavelength of from about 620 nm to about 650 nm, and at a fourth wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the approximate relative contribution of melanin to such perceived pigmentation by using the calculated absorbance of the third wavelength and the fourth wavelength at such area of skin; and (iii) determining the approximate relative contribution of deoxy-hemoglobin by subtracting the first approximate relative contribution of melanin from the calculated absorbance value at the first wavelength and the second wavelength.

**[0012]** Other features and advantages of the present invention will be apparent from the detailed description of the invention and from the claims.

## BRIEF DESCRIPTION OF FIGURES

### [0013]

Fig 1a is a graph showing the change in concentration of oxy-hemoglobin at various SSR dosages.

Fig 1b is a graph showing the change in concentration of deoxy-hemoglobin at various SSR dosages.

Fig 1c is a graph showing the change in concentration of melanin at various SSR dosages.

Fig 2 is a graph showing the change in concentration of oxy-hemoglobin, deoxy-hemoglobin, melanin, and scattering at various applied pressures.

Fig 3 is a graph showing that perception of "skin pigmentation" depends on deoxy-hemoglobin concentration in a similar fashion to its dependence on melanin.

Fig 4 is graph showing the change in concentration of oxy-hemoglobin, deoxy-hemoglobin, melanin, and scattering following topical application of 3% H<sub>2</sub>O<sub>2</sub>

## DETAILED DESCRIPTION OF THE INVENTION

**[0014]** It is believed that one skilled in the art can, based upon the description herein, utilize the present invention to its fullest extent. The following specific embodiments are to be construed as merely illustrative, and not limitative of the remainder of the disclosure in any way whatsoever.

[0015] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention belongs.

[0016] The present invention relates to a method of approximating the relative contribution of melanin and/or deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin. What is meant by the term "relative contribution" is either the (i) the concentration of the chromophore (e.g., melanin or deoxy-hemoglobin) at such area of skin or (ii) the percentage of the perceived pigmentation that is a result of the presence of such chromophore at the area of skin. Examples of pigmented areas of the skin include, but are not limited to, freckles, age spots, hyperpigmentation, dark circles, or tanned skin). The methods of the present invention utilize the absorbance of light at various wavelengths. What is meant by the phrase "a light at a wavelength" is radiation band centered at the specified wavelength wherein such band has a full width at half-maximum intensity of less than about 10 nm (e.g., for example less than about 5 nm).

[0017] The methods and devices of the present invention can be used to determine the source(s) of perceived pigmentation on areas of the skin. For example, if it is determined that the melanin contributes to the perceived pigmentation, skin lightening/depigmenting agents can be used to treat the area. Examples of such agents include, but are not limited to, ascorbic acid, kojic acid, and soy extracts. If it is determined that the deoxy-hemoglobin contributes to the perceived pigmentation, vasoactive agents can be used to treat the area. Examples of such agents include cortisone and hydrogen peroxide.

[0018] Objective quantitative evaluation of skin color using non-invasive instrumentation has been used since the early decades of the 20<sup>th</sup> century (Brunsting, L. A. and C. Sheard, (1929), *J Clin Invest* 7(4): 575-592). Since then spectrophotometers have become smaller and simpler in use. Many researchers have used methods based on reflectance measurements that either give "erythema" and "pigmentation" indices based on simple calculations (Diffey, et al., (1984) *Br J Dermatol* 111:663-672) or calculate tri-stimulus values ( $L^*a^*b^*$  scale) that have been adopted by the international committee of standards (CIE) as the preferred method for color measurement (Westerhof, et al., (1986) *Photodermatol*, 3:310-314). In the latter method,  $L^*$  and  $b^*$ , as well as combinations of the two, have been used as "pigmentation" parameters, and  $a^*$  as the "erythema" parameter. Recent studies have showed that in both methods what is clinically perceived erythema and pigmentation does not correlate linearly with the calculated indices (Takiwaki, et al., (2002), *Skin Res Techn* 8:78-83 and Wagner et al., (2002), *Pigment Cell Res*, 15:5:379-384). A more accurate method is to analyze the remitted spectrum to its constituents based on Diffuse Reflectance Spectroscopy (DRS) (Kollias, et al., *Clin. Dermatol.* 13:36 (1995)). Apparent concentrations of melanin, oxy-Hb, and deoxy-Hb can be extracted from absorption spectra obtained by DRS, thus separating the vascular from the melanin reactions that are responsible for erythema and pigment. DRS measurements are rapid, non-invasive, objective, and quantitative. Instruments that perform DRS can be small, portable, and easy to use.

[0019] The absorbance curve was calculated as the logarithm of the ratio of the diffuse reflectance from a non-irradiated site to the diffuse reflectance from an irradiated site. In previous algorithms, pigment was evaluated from the absorbance curve as the slope of the fitted straight line over the wavelength range of 620-720 nm. Then, the absorbance curve was corrected for the pigment absorption and, finally, the oxy-Hb and deoxy-Hb absorption curves were fitted in the range of 550-580 nm, where they exhibit maxima. Such algorithms, however, over-estimate the contribution of melanin and under-estimate the contribution of hemoglobin to the perceived pigmentation.

[0020] It has been assumed that deoxy-hemoglobin contributes to the "red" color in skin just like oxy-hemoglobin, afterall, both of these chromophores appear red in vitro. Deoxy-hemoglobin in skin is found in the superficial venous plexus and in particular in the venules. These vessels are large enough (20-50 microns in diameter) so that light (in the yellow-green part of the spectrum) is almost completely attenuated when it tries to traverse through them. This means that they appear dark (almost black) and slightly reddish. Slight occlusion of blood flow or compression of venules causes an increase or a decrease in the amount of deoxy-hemoglobin resident in the venules and therefore a change in the color of the skin. A surprising result was that these changes in concentration of deoxy-hemoglobin in the skin appear like changes in melanin pigment.

[0021] The main reason why deoxy-hemoglobin contributes to a pigmented skin appearance is that the absorption spectrum of deoxy-hemoglobin in the 630-700 nm range is very similar to the absorption spectrum of epidermal melanin, so whatever light is transmitted has the color balance of pigment. Furthermore, the size of the vessels in the superficial venous plexus is such that the transmitted radiation through these vessels is approximately 50% lower than the incident intensity, and, therefore, they appear dark. Moreover, deoxy-hemoglobin is a dominant pigment in normal skin, contributing 30-50% to the perceived concentration of blood and equal in its contribution to that of oxy-hemoglobin and melanin to skin color.

#### Device for Reflectance Acquisition

[0022] In one embodiment, the reflectance acquisition can be accomplished by either point spectroscopy or multi-spectral imaging. In the case of point spectroscopy, the system can, in one embodiment, include a light source, a probe, and a reflectance detector. In one embodiment, the light source is a broad-band source that includes wavelengths from



about 560 to about 780 nm. Examples of such broadband sources include, but are not limited to, incandescent light sources, metal-halide light sources, halogen lamps, and broad-band light emitting diodes (LEDs). In one embodiment, the light source is a monochromatic or narrow band source (e.g., emitting a wavelength or wavelengths of light substantially within the range of from about 560 to about 780 nm). Examples of such light sources include, but are not limited to, tunable lasers, narrow-band LEDs, and filtered broad-band sources. A combination of two or more of the above light sources can also be used. Examples of the probes include, but are not limited to, a fiber optic bundle (e.g., for contact with the skin site of interest) or an integrating sphere (e.g., with an opening that comes in contact with the site of interest). In the case of an integrating sphere, care should be taken to account for the contribution of specular reflection to the total reflected signal. In the case where a broad-band light source is used, a dispersive element (such as a grating or a monochromator), or a filter (such as a narrow band interference filter or a liquid crystal tunable filter) should be used to filter the light prior to entering the detector (e.g., to filter the light prior to contact with the skin or to filter the reflected light off the skin prior to entering the detector). Examples of detectors include, but are not limited to, a single photodiode, a photodiode array, a CCD array, or a photomultiplier.

**[0023]** In the case of multispectral imaging (e.g., a series of images acquired at a selected few wavelengths of interest), the system can include a light source and an imaging detector. Examples of light sources include, but are not limited to, broadband or narrow band sources capable of illuminating the area of interest or a combination of light sources as discussed above. The detector can be a digital camera, such as a CCD or CMOS. In the case of broadband light source, the image needs to be filtered before reaching the detector to the appropriate wavelengths. In one embodiment, filtering can be accomplished by placing appropriate dispersive element or filter between the light source and the detector to filter the light entering the detector. In one embodiment for multispectral imaging, orthogonal polarization between the illumination and the detector is used in order to eliminate specular reflection (e.g., glare). Orthogonal polarization can be accomplished by placing a linear polarizer in front of the light source and a second linear polarizer in front of the detector (e.g., the camera). The second linear polarizer can be placed in such a way that its polarization plane is orthogonal to the polarization plane of the first linear polarizer.

#### Algorithm for Analysis of Absorbance

**[0024]** Applicants have discovered a new corrected algorithm for the analysis of reflectance spectra from skin that separates the approximate vascular from the approximate melanin contributions to the perceived erythema and/or pigmentation by taking into account the spectral contribution of deoxy-Hb in the red region of the spectrum (620-700 nm). In one embodiment, the procedure is as follows: (a) the diffuse reflectance spectrum from skin is referenced to uninvolved normal skin of the same individual, (b) the spectrum is fitted with a straight line in wavelength ( $f(\lambda)$ ) in the spectral range 620-720 nm (the slope of the straight line is believed to be related to the concentration of melanin in the skin); (c) the straight line that best fits the data is then subtracted from the whole spectrum, which results in a spectrum that is identical with the baseline at wavelengths in the range 620-720 nm and deviating from baseline to shorter wavelengths; (d) the difference spectrum is fitted using the absorption parameters of oxy-hemoglobin and deoxy-hemoglobin at the wavelengths of 560 and 578 nm, which is accomplished by solving a system of two equations and two unknowns, the result is an apparent concentration of oxy-hemoglobin and of deoxy-hemoglobin; (e) the concentration of deoxy-hemoglobin is used to calculate the contribution of this chromophore to the measured slope of the fitted line of step (b); (f) the apparent concentration of melanin is related to the slope of the line of step (b) corrected for the absorption of deoxy-hemoglobin in this wavelength range given by step (e); (g) an apparent scattering parameter can be calculated from the value of the corrected fitted line of step (f) at an arbitrary selected wavelength in the range of 630 - 820 nm; (h) the corrected fitted line of step (f) is subtracted from the whole spectrum (similarly to step (c)), and (i) the new difference spectrum is fitted using the absorption parameters of oxy-hemoglobin and deoxy-hemoglobin at the wavelengths of 560 and 578 nm (similarly to step (d)), which is accomplished by solving a system of two equations and two unknowns, the result is the corrected apparent concentration of oxy- and of deoxy-hemoglobin.

**[0025]** In one embodiment of the algorithm, the above steps can be condensed to the following equations:

**[0026]** The intercept ( $\text{int}_o$ ) and the slope ( $m_o$ ) of the absorbance spectra in the 620 - 720 nm range can be calculated from the values of the spectrum at the wavelengths 620 nm and 720 nm ( $S^{620}$  and  $S^{720}$  correspondingly):

$$\text{int}_o = \frac{720 \times S^{620} - 620 \times S^{720}}{720 - 620}, \quad m_o = \frac{S^{720} - S^{620}}{720 - 620} \quad (1)$$

**[0027]** The absorbance values at 560 and 578 nm corrected for melanin (initial approximation) are given by:

$$S_c^{560} = S^{560} - (m_o \times 560 + \text{int}_o), \quad S_c^{578} = S^{578} - (m_o \times 578 + \text{int}_o) \quad (2)$$

**[0028]** The concentrations of oxy-Hb ([HbO<sub>2</sub>]) and deoxy-Hb ([Hb]) can be calculated from these corrected values of the absorption spectrum and the extinction coefficients of oxy-Hb and deoxy-Hb at 560 nm and 578 nm,  $\alpha_{HbO_2}^{560}$ ,  $\alpha_{HbO_2}^{578}$ ,  $\alpha_{Hb}^{560}$ , and  $\alpha_{Hb}^{578}$ :

$$[HbO_2] = \frac{\alpha_{Hb}^{560} \times S_c^{578} - \alpha_{Hb}^{578} \times S_c^{560}}{\alpha_{Hb}^{560} \times \alpha_{HbO_2}^{578} - \alpha_{Hb}^{578} \times \alpha_{HbO_2}^{560}}, \quad [Hb] = \frac{\alpha_{HbO_2}^{578} \times S_c^{560} - \alpha_{HbO_2}^{560} \times S_c^{578}}{\alpha_{Hb}^{560} \times \alpha_{HbO_2}^{578} - \alpha_{Hb}^{578} \times \alpha_{HbO_2}^{560}} \quad (3)$$

The approximate relative contribution of oxy-hemoglobin and deoxy-hemoglobin can be used to examine vascular components of the skin and its related skin conditions, such as erythema, acne, inflammation, rosacea, and spider veins.

**[0029]** Finally, the corrected melanin concentration can be calculated given the slope of the deoxy-Hb extinction coefficient in the range 620-720 nm,  $S_{Hb}^{620-720}$ :

$$[melanin] = m_o - [Hb] \times S_{Hb}^{620-720} \quad (4)$$

The corrected values for oxy-Hb and deoxy-Hb concentrations can be calculated from equations (2) and (3) after substituting  $m_o$  with the corrected melanin concentration given in equation (4).

**[0030]** The approximate relative contribution of the light scattering can be calculated from:

$$SC = m_o \times \lambda_{sc} + \text{int}_o \quad (5)$$

where  $\lambda_{sc}$  is the chosen wavelength in the range 630-820nm. The approximate relative contribution of scattering can be used to examine dermal collagen and its related skin conditions, such as wrinkles and fine lines.

**[0031]** The above algorithm can be applied to point spectroscopy as well as to hyper- or multi- spectral imaging. Hyper-spectral imaging refers to a series of images acquired at different wavelengths, in such a way that a spectrum can be reconstructed for each individual pixel of the image based on the intensity values of the particular pixel throughout the wavelength range of acquisition. Multi-spectral imaging refers to a series of images acquired at a selected few wavelengths of interest.

**[0032]** Before any analysis of the hyper- or multi-spectral images takes place, care should be taken that the spectral images are registered to cancel any motion artifacts that may have occurred during image acquisition. In one embodiment, image registration includes image translation and rotation, but not image dilation, as the latter may compromise the quantitative nature of the algorithm.

**[0033]** In the case of hyper-spectral imaging, the plot of the intensity value of a pixel versus the acquisition wavelength is equivalent to a reflectance spectrum (scaled from 0 to 255 for 8 bit images) of the imaged object at the spatial position of the pixel. The following procedure describes, in one embodiment, how to convert the hyper-spectral spectrum of a pixel to an absorbance spectrum: (a) the percent reflectance spectrum is calculated by taking the ratio of the pixel intensity values to either the maximum allowed intensity (255 for 8 bit images), the reflectance from a white standard, or an image from a wavelength from about 800 to about 900 nm; (b) the estimated specular reflectance is subtracted from the ratio of step (a) (specular reflectance is given by the Fresnel law and for human skin this value is approximately 0.04); and (c) the negative logarithm of the corrected ratio of step (b) plotted against the acquisition wavelengths is the resulting absorbance spectrum.

**[0034]** Once the absorbance spectrum has been calculated, the procedure described above can be used to evaluate the chromophore values at each pixel. After normalization (byte scaling), the values of each chromophore for all pixels can be displayed as separate images, also referred to as "chromophore maps." See, e.g., Stamatas et al., (2003) Proc. SPIE 4959:77-82 for chromophore maps calculated by a previous algorithm.

**[0035]** In one embodiment, a similar "curve-fitting" procedure can be used to calculate apparent values of other chromophores native to human skin or externally applied. Some examples of native pigments not mentioned above include, but are not limited to, methemoglobin (absorbance at 404 nm and 635 nm), bilirubin (absorbance at 460 nm), beta-carotene, and water (absorbance bands at 970 nm, 1100 nm, etc.). Externally applied chromophores include, but

are not limited to, materials that absorb in UV, visible, or NIR, such as sunscreens, cosmetic formulations, make-up, lipstick, and topical drugs. Thus, a similar approach can be used to quantify deposition of an ingredient of a topical formulation.

**[0036]** Alternatively to hyper-spectral imaging a small number of acquisition wavelengths can be selected that would result in chromophore maps using the above procedure. This approach is termed multi-spectral imaging. The requirements for selecting the right acquisition wavelengths are as follows: (a) One image is required to be acquired in the wavelength region of the deoxy-hemoglobin maximum at 560 nm and has to have a bandwidth of less than 5 nm at each side, in order to avoid the maxima of oxy-hemoglobin at 555 nm and 578 nm; (b) One image is required to be acquired in the wavelength region of the beta band of oxy-hemoglobin (at 578 nm) and has to have a bandwidth of less than 10 nm at each side; and (c) At least two images are required to be acquired in the wavelength region of 620 nm - 720 nm with the wavelengths being chosen as far from each other as possible to cover evenly the region.

**[0037]** Melanin and scattering values can be calculated from the (c) images as described in the procedure above and oxy- and deoxy-hemoglobin values from a 2x2 system using the intensities of images (a) and (b). To calculate values for the four chromophores mentioned here, a minimum of four images at different wavelengths should be used.

### Clinical Studies

**[0038]** Twelve healthy individuals with skin photo-types III-IV participated in the study. The source of irradiation was a 500W UVC-filtered Xenon arc solar simulator (Solar Light Co., Philadelphia, PA). The instrument was calibrated right before its use, and the total power of the source was recorded every 3 to 4 hours throughout the day to assure its stability and spectral quality following Colipa (The European Cosmetic, Toiletry, and Perfumery Association) guidelines. Initially the minimum solar simulator radiation (SSR) dose to induce perceptible erythema (MED) was determined on the back of each participant. Clinical erythema was evaluated 24 hours after the irradiation. Following MED determination, each individual was irradiated on the back with SSR doses of 0.7, 1.0, 1.5, 2.1, and 3 MED. The skin reactions were evaluated on days 1, 7, 14, and 21 after exposure. Evaluations included cross-polarized photography, DRS measurements, and clinical assessment of erythema and pigmentation by an experienced dermatologist.

**[0039]** In a second experiment, a pressure cuff was applied to the upper arm of ten healthy volunteers. The applied pressure was set at levels of 0, 20, 30, 40, and 60 mmHg. Measurements were taken 5 min after each pressure level was set to allow for the vasculature to equilibrate. Changes in skin color due to vascular reactions were evaluated visually with a chromameter and with a DRS instrument.

**[0040]** In a third experiment, 2 inch diameter cotton pads soaked in 3% H<sub>2</sub>O<sub>2</sub> (U.S.P. topical anti-infective) in aqueous solution were applied on the volar forearm of ten healthy volunteers for 1 min. The pads were removed and the skin area was dried with fresh cotton pads. DRS measurements and visible evaluation of the treated sites were performed at 0, 5, 10, 15, and 20 min after removal of the pads.

### Diffuse Reflectance Spectroscopy (DRS)

**[0041]** The DRS instrument contained a quartz halogen light source (Ocean Optics, Boca Raton, FL), a bifurcated fiber bundle (Multimode Fiber Optics, East Hanover, NJ), an S2000 spectrometer (Ocean Optics, Boca Raton, FL), and a laptop computer (Toshiba Tecra, Irvine, CA). One leg of the fiber bundle was connected to the light source and the other to the spectrometer. Measurements were performed by placing the common end of the fiber bundle gently in contact with skin so as not to perturb the blood content. A reflectance spectrum was acquired in the range of 400-820 nm. Apparent concentrations of hemoglobin and melanin were calculated from the diffuse reflectance spectra. See, e.g., Kollias et al., Photodermatol 5:53-60 (1988). Briefly, the absorbance curve was calculated as the logarithm of the ratio of the diffuse reflectance from a non-irradiated site to the diffuse reflectance from an irradiated site. Pigment was evaluated from the absorbance curve as the slope of the fitted straight line over the wavelength range of 620-720 nm. Then, the curve was corrected for the pigment absorption, and finally, the oxy-Hb and deoxy-Hb absorption curves were fitted in the range of 550-580 nm, where they exhibit maxima, as set forth in Table 1.

Table I

Chromophore	Absorption curve characteristic
Melanin	Monotonic increase towards short wavelengths; Approximates linear in the region 600 - 750 nm
Oxy-Hemoglobin	Maxima at 415, 540, and 577 nm
Deoxy-Hemoglobin	Maxima at 430 and 555 nm

[0042] The reproducibility of the method for calculating apparent hemoglobin concentrations was calculated as the error between measurements, and it was found to be better than 10%. It needs to be noted that for the collection geometry used here, an underestimation of the reflectance at the long wavelengths (red/NIR region) compared to the shorter wavelengths (blue/green region) is anticipated. However, the measurements were always performed relative to baseline, or to neighboring untreated skin, and, therefore, such artifacts have been normalized.

#### Data Analysis

[0043] Linear regressions of the data were calculated using the least square errors algorithm. The goodness of fit is given by the correlation coefficient (R-squared). Statistical significance was calculated using the Student's t-test for paired data distributions.

#### UV Irradiation Experiment

[0044] UV-induced erythema was typically evaluated on day 1 after irradiation, while pigmentation was evaluated on day 7. The time course of changes in the concentration of oxy-Hb, deoxy-Hb, and melanin are shown in Figs 1a, 1b, and 1c. On day 1, after irradiation the observed skin reaction was classified as clinical "erythema". The visual observation of erythema correlated well with a dramatic increase in oxy-Hb and deoxy-Hb, as calculated from the spectroscopic data (Figs. 1a and 1b). The observed skin reaction on day 7 was classified clinically as "pigmentation", which correlated with an increase in melanin (Fig. 1c). However, the levels of both hemoglobins were significant on day 7, indicating that there is a strong vascular contribution to the observed reaction (Figs. 1a and 1b). On day 14, the reaction was again classified as "pigmentation", and although the melanin levels remained elevated, the concentration of deoxy-Hb was still above baseline (Fig. 1b). On day 21, the observed pigmentation was almost exclusively due to melanin (Fig. 1c). Although deoxy-Hb is still measurably above baseline, its contribution at 0.1 level was not visibly perceptible.

#### Pressure cuff experiment

[0045] In the pressure cuff experiment, increasing pressure resulted in a reduction of the values of  $L^*$  and  $b^*$  as measured by the chromameter corresponding to darker and less yellow color respectively. On the contrary, the value of  $a^*$  increased corresponding to a more red appearance. Although the color changes were recorded with the chromameter, it is of interest to note that visually the change in skin color was hard to observe. The reason was that the human eye works better in contrast and since the pressure was applied on the whole of the arm, the color change was uniform and, therefore, difficult to detect. DRS analysis showed that the only chromophore that was affected by changing the applied pressure was deoxy-Hb, which increased linearly with pressure (Fig. 2). Oxy-Hb and melanin remained practically unaltered. The characteristic angle,  $\alpha = \arctan((L^*-50)/b^*)$ , is a measure of the perceived pigmentation in such a way that when apparent pigmentation increases this parameter decreases. See, e.g., Park, et al., Clinexp Dermatol 24:315-320 (1999). In the present experiment, the characteristic angle decreased with increasing pressure in all volunteers, indicating that pressure-induced increases in blood stasis can be perceived as increased pigmentation (Fig. 3).

#### Hydrogen Peroxide Experiment

[0046] Application of cotton pads soaked in 3% hydrogen peroxide for 1 min induced a decrease in perceptible skin pigmentation that lasted for 10-15 min after removal of the pads. Analysis of DRS spectra showed that deoxy-Hb significantly decreased during the period of blanching (Fig. 4). Oxy-Hb decreased slightly, but within instrument variability (determined to be  $\pm 0.1$  oxy-Hb units). Melanin and dermal scattering remained unchanged at baseline levels.

[0047] It is understood that while the invention has been described in conjunction with the detailed description thereof, that the foregoing description is intended to illustrate, and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the claims.

#### Claims

1. A method of approximating the relative contribution of melanin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of (i) determining the absorbance of light at a wavelength of from 620 nm to 750 nm at said area of skin and (ii) subtracting the approximate relative contribution of deoxy-hemoglobin from said absorbance.

2. A method of claim 1, wherein said method comprises determining said absorbance of light at least two different wavelengths, wherein said wavelengths are from 620 nm to 750 nm.
- 5 3. A method of claim 1 or claim 2, wherein the approximate relative contribution of deoxy-hemoglobin is determined by determining the absorbance of light at a wavelength from 550 nm to 590 nm at said area of skin.
- 10 4. A method of approximating the relative contribution of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of (i) determining the absorbance of light at a wavelength of from 550 nm to 590 nm at said area of skin and (ii) subtracting the approximate relative contribution of oxy-hemoglobin and melanin from said absorbance.
- 15 5. A method of claim 4, wherein said method comprises determining said absorbance of light at least two different wavelengths, wherein said wavelengths are from 550 nm to 590 nm.
- 20 6. A method of claim 4 or claim 5, wherein the approximate relative contribution of melanin is determined by determining the absorbance of light at a wavelength from 620 nm to 750 nm at said area of skin.
- 25 7. A method of approximating the relative amount of melanin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of:
  - (i) measuring the reflectance of a first light at a wavelength of from 555 nm to 565 nm, a second light at a wavelength of from 570 nm to 585 nm, a third light at a wavelength of from 620 nm to 650 nm, and a fourth light at a wavelength of from 680 nm to 750 nm at said area of skin;
  - (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of said third light and said fourth light at said area of skin;
  - (iii) subtracting said first approximate relative contribution of melanin from the determined absorbance of said first light and said second light at said area of skin;
  - (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of said first light and said second light of step (ii); and
  - 30 (v) subtracting the first approximate relative contribution of deoxy-hemoglobin from said first approximate relative contribution of melanin to obtain a final approximate relative contribution of melanin.
- 35 8. A method of approximating the relative amount of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of:
  - (i) measuring the reflectance of a first light at a wavelength of from 555 nm to 565 nm, a second light at a wavelength of from 570 nm to 585 nm, a third light at a wavelength of from 620 nm to 650 nm, and a fourth light at a wavelength of from 680 nm to 750 nm at said area of skin;
  - (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of said third light and said fourth light at said area of skin;
  - 40 (iii) subtracting said first approximate relative contribution of melanin from the determined absorbance of said first light and said second light at said area of skin; and
  - (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of said first light and said second light of step (iii).
- 45 9. A method of approximating the relative contribution of melanin to a perceived pigmentation of an area of skin, said method comprising the steps of:
  - (i) examining said area of skin with a device comprising a light source and a reflectance detector, wherein said detector measures the reflectance from said area of skin of light generated by said light source of at a first wavelength of from 555 nm to 565 nm, at a second light wavelength of from 570 nm to 585 nm, at a third wavelength of from 620 nm to 650 nm, and at a fourth wavelength of from 680 nm to 750 nm at said area of skin,
  - (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by using the calculated absorbance of said third wavelength and said fourth wavelength at said area of skin; and
  - 50 (iii) further determining the approximate relative contribution of melanin by subtracting from said first approximate relative contribution of melanin the approximate relative contribution of deoxy-hemoglobin determined by the absorbance of said first wavelength and said second wavelength at said area of skin.

10. A method of approximating the relative contribution of deoxy-hemoglobin to a perceived pigmentation of an area of skin, said method comprising the steps of:

- (i) examining said area of skin with a device comprising a light source and a reflectance detector, wherein said detector measures the reflectance from said area of skin of light generated by said light source of at a first wavelength of from 555 nm to 565 nm, at a second light wavelength of from 570 nm to 585 nm, at a third wavelength of from 620 nm to 650 nm, and at a fourth wavelength of from 680 nm to 750 nm at said area of skin; (ii) determining the approximate relative contribution of melanin to such perceived pigmentation by using the calculated absorbance of said third wavelength and said fourth wavelength at said area of skin; and (iii) determining the approximate relative contribution of deoxy-hemoglobin by subtracting said first approximate relative contribution of melanin from the calculated absorbance value at said first wavelength and said second wavelength.

11. A method of any one of claims 7 to 10, wherein said device comprises a filter device such that the light emitted from said light source is filtered to said first wavelength, said second wavelength, said third wavelength, and said fourth wavelength, optionally prior to measurement by said reflectance detector.

12. A method of any one of claims 7 to 11, wherein said reflectance detector is a spectrometer.

13. A method of any one of claims 7 to 11, wherein said reflectance detector is a camera.

14. A method of claim 13, wherein said method is conducted at a plurality of areas of the skin where the absorbances at such areas of skin are determined from the pixels obtained by said camera.

15. A method of claim 14, wherein said relative contribution of melanin or deoxy-hemoglobin at said areas of skin is represented as an image of such areas of skin.

FIG. 1a

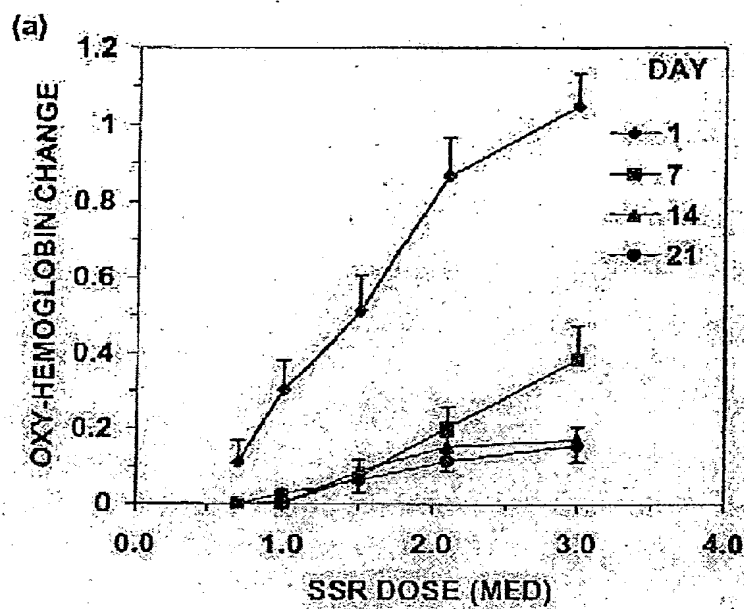


FIG. 1b

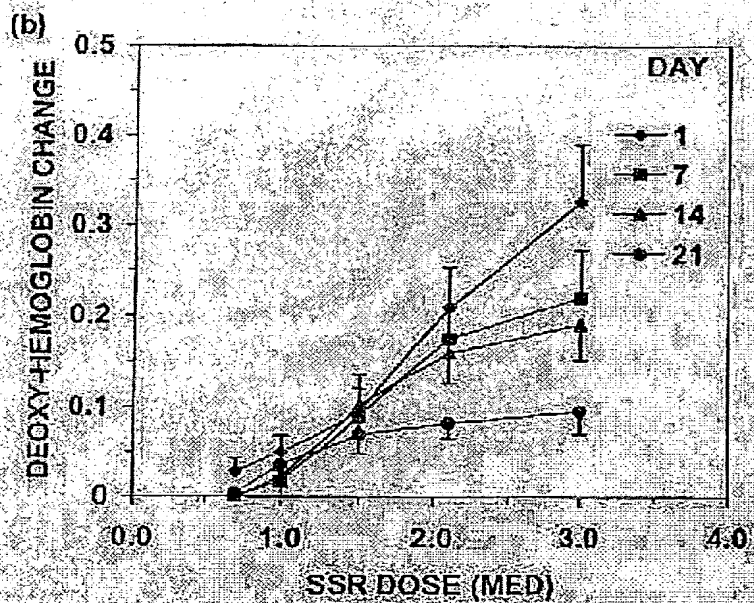


FIG. 1c

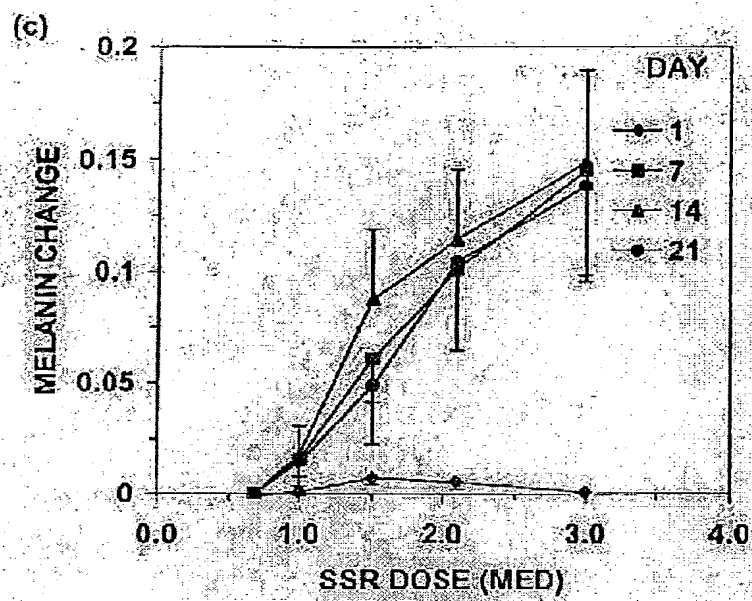




FIG. 2

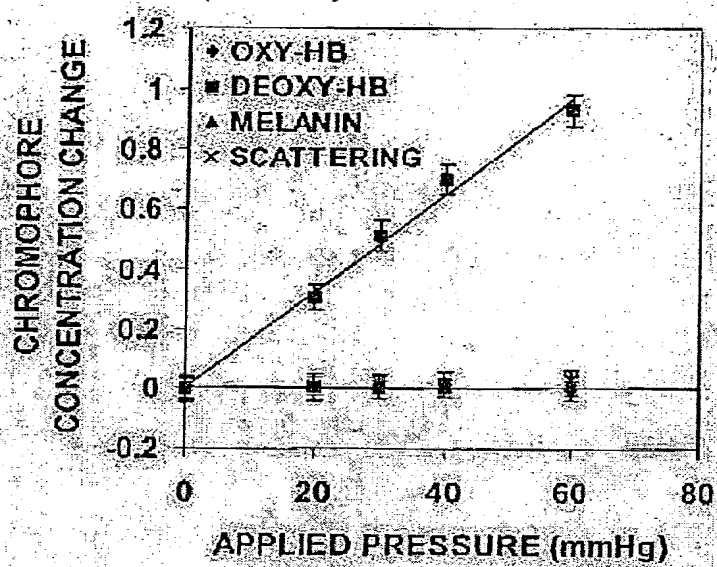


FIG. 3

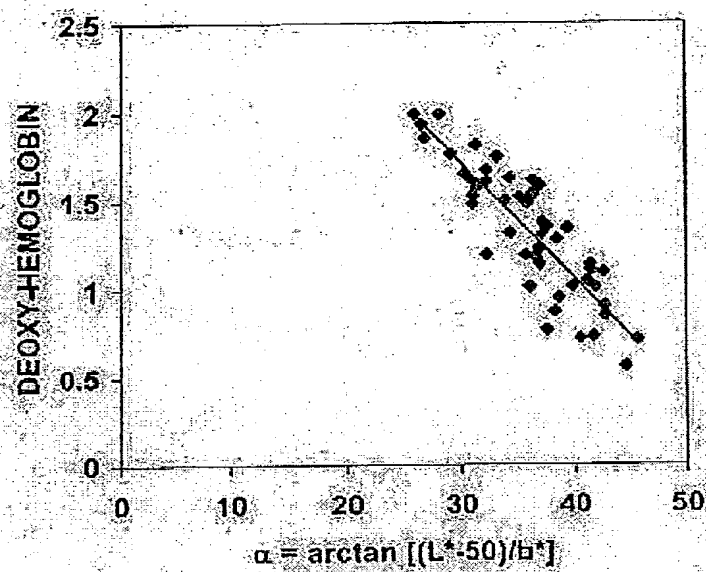
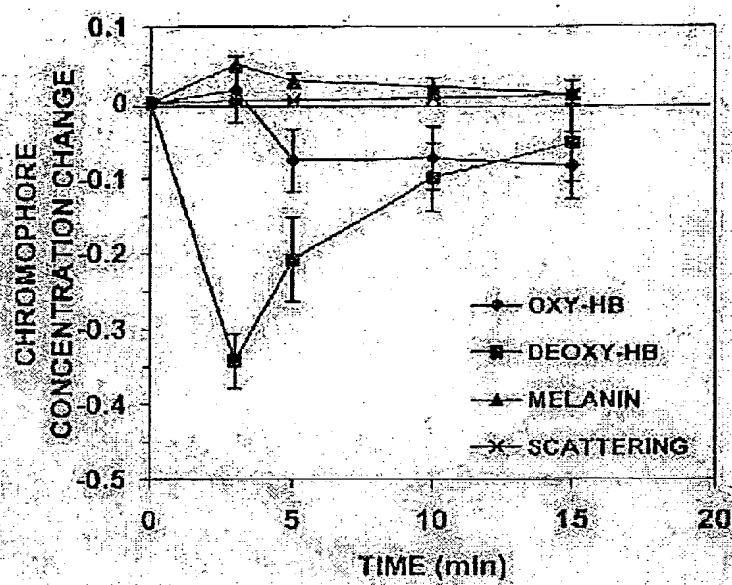


FIG. 4





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# EUROPEAN SEARCH REPORT

Application Number  
EP 04 25 5139

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Place of search Munich		Date of completion of the search 29 October 2004	Examiner Willig, H
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document</p> <p>T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons &amp;: member of the same patent family, corresponding document</p>			

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EPO FORM 1503 03.82 (P04001)



European Patent  
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# EUROPEAN SEARCH REPORT

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CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document		T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons &: member of the same patent family, corresponding document	

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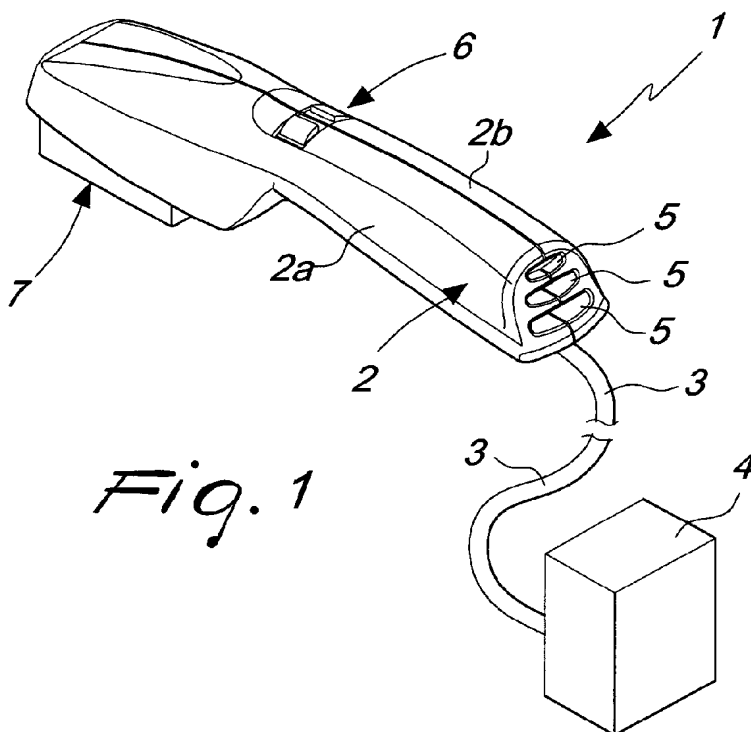
(30) Priority: **27.11.2003 IT bo20030717**

(71) Applicant: **ESPANSIONE MARKETING S.P.A.**  
**40050 FUNO DI ARGELATO BO (IT)**

(54) **Light irradiation unit for diagnosing and treating skin problems**

(57) A light irradiation unit (1), of the type that comprises a control processor (4) and a handpiece (2), which is connected electrically to the processor (4) and is provided with a light source and with at least one filter that is interposed between the source and a front opening of the handpiece (2) for the exit of the light. The handpiece (2) is enclosed by two symmetric half-shells (2a,

2b), which are mutually coupled so as to constitute a chamber, and the light source and the filter are fitted on a cartridge (7) that can be inserted in a portion of the chamber; the cartridge (7) is associable within the portion by way of locking means. A plate made of a material that is permeable to light radiation is fitted on the cartridge (7) proximate to the filter and parallel thereto.



*Fig. 1*

## Description

**[0001]** The present invention relates to a light irradiation unit for diagnosing and treating skin problems and for hair removal treatments.

**[0002]** By subjecting the skin to light beams of various intensities and various duration, it is possible to obtain from said skin information regarding its state and characteristics, which can be used for diagnostic purposes.

**[0003]** Further, different combinations of light irradiation of the skin can facilitate the reduction of some kinds of dermatological disorder and improve their aesthetic appearance. For example, with treatments of this kind it is possible to eliminate or reduce the number of fine capillary vessels (telangiectasias) and to provide permanent or semipermanent hair removal on the treated surfaces.

**[0004]** Devices are commercially available which are provided with a lamp commonly used for flashing luminous indicators (for example sirens with flashing lamp for flying-squad vehicles), which has a higher power because it has not only a visual effect but also a heat generation effect.

**[0005]** The lamp is fitted inside a mirror-finished parabolic reflector, which causes the light to converge toward a specific point on the skin. All this is inserted within a handpiece provided with a button for activating the emission of light radiation.

**[0006]** The lamp emits radiation with a very broad wavelength range, from the ultraviolet to the infrared; accordingly, a filter that allows only the radiation of the intended wavelength to pass is installed and interposed between the lamp and the skin.

**[0007]** During operation, the lamp emits heat and accordingly gets hot and also heats the skin excessively.

**[0008]** In currently commercially available devices, the handpiece in which the lamp is mounted is cooled by means of a suction circuit; the skin of the patient is located proximate to the filter that shields the light source and is therefore struck by an intense flow of heat.

**[0009]** It should be noted that the filter can be touched both intentionally (for example by inserting a finger in the front opening from which the light flashes exit) and unintentionally (for example by treating a curved skin portion and pressing the handpiece excessively against said skin, one runs the risk of contact between the skin and the surface of the filter).

**[0010]** Contact with the filter (which can reach high temperatures) certainly entails skin burns: therefore, this apparatus must be used with great skill and cannot be left unattended in the presence of the patient (especially after use, when the filter is still hot and burns are possible if it is handled incorrectly).

**[0011]** The lamp and the filter constitute an assembly by means of which it is possible to treat only some aesthetic problems: it is convenient to associate various filters with a same type of light source or to vary both the source and the filter to obtain a series of assemblies suit-

able for all kinds of skin and for all kinds of treatment.

**[0012]** Currently, the entire handpiece is replaced by adopting the one that is most suited for the type of skin and the type of treatment: this entails the purchase of a certain number of handpieces, which however are very expensive and bulky.

**[0013]** There are constructive solutions which use interchangeable lamp-filter assemblies: rapid replaceability allows far easier use, but over time it can entail wear of the parts that slide with respect to each other during replacement, rendering the coupling of the assembly to the handpiece scarcely stable.

**[0014]** The aim of the present invention is to obviate the cited drawbacks and meet the mentioned requirements, by providing a light irradiation unit in which contact with the filter is not possible and in which it is possible to ensure rapid replacement and anchoring of the filter and the lamp.

**[0015]** Within this aim, an object of the present invention is to provide a unit in which localized cooling of the handpiece is provided in order to keep at a low temperature all the parts that make contact with the operator and the patient.

**[0016]** Another object of the present invention is to provide a unit that is simple, relatively easy to provide in practice, safe in use, effective in operation, and has a relatively low cost.

**[0017]** This aim and these and other objects that will become better apparent hereinafter are achieved by the present light irradiation unit, of the type that comprises a control processor and a handpiece, which is connected electrically to said processor and is provided with a light source and with at least one filter that is interposed between said source and a front opening of said handpiece for the exit of the light, characterized in that said handpiece is enclosed by two symmetric half-shells, which are mutually coupled so as to constitute a chamber, in that said light source and said filter are fitted on a cartridge that can be inserted in a portion of said chamber, said cartridge being associable within said portion by way of locking means, and in that a plate of a material that is permeable to light radiation is fitted on said cartridge proximate to said filter and parallel thereto.

**[0018]** Further characteristics and advantages of the present invention will become better apparent from the following detailed description of a preferred but not exclusive embodiment of a light irradiation unit, illustrated by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a top perspective view of a handpiece of a unit according to the invention;

Figure 2 is a partially sectional bottom perspective view of a handpiece of a unit according to the invention;

Figure 3 is a bottom perspective view of a handpiece during the extraction of a cartridge of a unit according to the invention;



Figure 4 is a sectional front view of a handpiece of a unit according to the invention, in which the half-shells are spaced;

Figure 5 is a sectional front view of a handpiece of a unit according to the invention, in which the half-shells are closed together;

Figure 6 is a top rear perspective view of a handpiece of a unit according to the invention, in which the half-shells are spaced;

Figure 7 is a bottom front perspective view of a handpiece of a unit according to the invention, in which the half-shells are closed together;

Figure 8 is a sectional rear view of a unit according to the invention, in which the half-shells are closed together;

Figure 9 is a perspective view of a lamp of a unit according to the invention;

Figure 10 is a plan view of a parabolic reflector of a unit according to the invention;

Figure 11 is a front top perspective view of a cartridge of a unit according to the invention;

Figure 12 is a bottom rear perspective view of a cartridge of a unit according to the invention.

**[0019]** With reference to the figures, the reference numeral 1 generally designates a light irradiation unit.

**[0020]** The unit 1 is constituted by a handpiece 2, which is connected by means of a multicore cable 3 to a control processor 4.

**[0021]** The handpiece 2 has an elongated shape, with smooth and radiused surfaces; at the rear, above the hole for the insertion of the cable 3, there are through slots 5. The actuation buttons 6 are provided in an upper region, at the central portion of the handpiece 2.

**[0022]** Each handpiece 2 is constituted by two half-shells 2a and 2b, which are mutually coupled by means of at least one screw 2c, which passes through the half-shell 2a and engages within an appropriately provided seat of the half-shell 2b.

**[0023]** A cartridge 7 is accommodated in the front part of the handpiece 2 and is provided with a plurality of front openings 8 and with at least one rear slot 8a (the openings 8 and the slot 8a allow the circulation of air within the cartridge 7). The cartridge 7 has the appearance of a block, with a flat bottom 9 made of a material that is not transparent to light radiation. Plates 7a are applied to the cartridge 7 and are constituted by a flat mask 10 provided with an opening 11. The cartridge 7 has, in an upper region, a transparent screen, the filter 12, which has a rectangular area with sides that measure respectively 50 and 30 mm; the filter 12 can be made of materials such as glass, quartz and sapphire but also of other plastic or ceramic materials or of other kinds of material having particular filtering actions with respect to light radiation. Beyond the filter 12, also above the cartridge 7, there is a phototype detector 13.

**[0024]** In the rear part of the cartridge 7 there are pins 14 for connection to the handpiece 2, which are suitable

to be coupled electrically to the connection socket 14a of the handpiece 2.

**[0025]** The cartridge 7 is constituted by a parabolic reflector 15. Inside the parabolic reflector 15 there is a receptacle 16 for a lamp 17, which is shaped like two parallel and mutually proximate cylinders which are radiused at two ends and end, at their opposite ends, with respective electrical contacts 18. The patient can be subjected to light radiation having a wavelength comprised between 1 and 2000 nanometers.

**[0026]** A cooling fan 19 is installed longitudinally inside the handpiece 2 in the rear part: when the fan 19 is active, it aspirates air through the holes 5 and conveys it through a duct (delimited between the bottom 9 of the cartridge 7 and the region that surrounds the lamp 17) toward a front opening constituted by the slots 8.

**[0027]** The entire cartridge 7 is detachable and can be replaced with other cartridges 7 that have different filters 12, suitable for performing different therapies. For removal, it is necessary to resort to the use of a wrench C, which engages in the head of the screw 2c: by loosening the screw 2c, the two half-shells 2a and 2b are moved mutually apart and the cartridge 7 is disengaged from the clamping action, allowing its extraction; the new cartridge 7, once arranged within the half-shells 2a and 2b so that the pins 14 engage in the connection socket 14a, is fastened between the half-shells 2a and 2b, preventing its movement, by re-tightening the screw 2c with the wrench C. A plate 7a is accommodated and superimposed above the cartridge 7, is made at least partially of a material that is permeable to light radiation, and is designed to prevent direct contact of the skin of the patient with the surface of the filter 12. The surface of the filter 12, although being separate from the lamp 17, is heated considerably by said lamp, and this makes it potentially dangerous for the skin of the patient. The presence of the plate 7a, which in turn is separated from the filter 12 by means of an air gap (through which the air is conveyed forcibly by means of the fan 19), provides assurance of the patient against the risk of burns. The plate 7a is flat and is provided with two perimetric bands 7b, which are arranged at right angles thereto and are provided with end protrusions 7c for anchoring to the side walls of the cartridge 7; the cartridge 7 has, along its side walls, proximate to the open surface, from which the filter 12 can be accessed, a pair of longitudinal grooves 7d, which are suitable to accommodate stably the protrusions 7c.

**[0028]** The phototype detector 13 is a very important accessory, which is used to detect the type of skin being treated at a given moment. There are various kinds of skin, according to a scale defined by Fitzpatrick; this scale defines the reaction of the skin subjected to the emission of light, such as for example sunlight. This classification defines six types of skin: a first type, which always burns; a second type, which burns occasionally; a third type, which burns and occasionally tans; a fourth type, which tans and occasionally burns; a fifth type,

which tans; and a sixth type, which tans and does not bum.

**[0029]** The phototype detector 13 allows to diagnose the patient's phototype, so as to subject the patient to the most suitable therapy.

**[0030]** The phototype detector 13 is arranged near the lamp 18, but can also be arranged in other parts or separately from the cartridge 7.

**[0031]** A temperature sensor is inserted in the cartridge 7 and is connected to the processor 4 for controlling and lighting the lamp 17; this allows to check that the lamp 17 does not exceed a certain temperature that might damage the assembly 7 and/or bum the skin of the patient being treated. The temperature sensor can be electronic, electric, electromechanical or of any type that has these functions.

**[0032]** Each cartridge 7 differs according to the type of filter 12 fitted therein; in order to recognize it, the assembly 7 is provided with an electronic recognition apparatus.

**[0033]** Since the filter 12 is a non-detachable part of the block 7, the problem of recognizing the filter 12 is reduced to the problem of recognizing the electric circuit of the block 7 on which it is installed.

**[0034]** The operation of the invention is as follows: once the therapy to which the patient is to be subjected is known, the type of assembly 7 suitable for said therapy is chosen and is inserted in the handpiece 2 by sliding the bottom 9 into the appropriately provided receptacle and by making the pins 14 mate with the socket 14a; the filter detector 12 indicates on a display the type of filter that is installed.

**[0035]** By pressing one of the buttons 6 arranged on the top of the handpiece 2, the phototype detector 13 is activated and identifies the characteristics of the skin of the patient, checking the reflection on the skin of the light radiation, emitted by a light source, by means of a photodiode. The result of the test is indicated on the display.

**[0036]** Depending on the characteristics of the skin of the patient, the operator selects the most suitable program and starts the treatment, keeping the handpiece 2 orientated so that the lamp 17 faces the portion of skin to be treated.

**[0037]** The temperature of the lamp 17 is monitored constantly by the temperature sensor, which sends a signal that is proportional to the temperature of the lamp 17 to the processor 4, which adjusts the duration and frequency of the flashes in succession to avoid overheating. If a temperature limit is reached, the processor 4 disables the operation of the lamp 17.

**[0038]** During operation, the cooling fan 19 operates and keeps the temperature of the lamp 17 low.

**[0039]** The simultaneous presence of cooling means that act locally (fan 19) and of a plate 7a that separates the skin of the patient from the high-temperature surfaces makes the handpiece very simple to use and protects the patient, avoiding the risk of burns.

**[0040]** The possibility to replace the cartridges 7

makes it easier for operators to perform the treatment; moreover, the need to fasten the inserted cartridge 7 each time gives the advantage of always achieving the correct insertion of the cartridge 7 in the handpiece 2, making sure that it cannot detach accidentally and fall (and thus certainly be damaged) or provide a poor contact between the pins 14 and the socket 14a, with consequent possible malfunction and damage of the circuits.

**[0041]** It has thus been shown that the invention achieves the intended aim and objects.

**[0042]** The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

**[0043]** For example, it is possible to block the cartridge 7 by way of other fastening means. By using a toggle lever that is articulated to a half-shell 2a and engages in a protrusion of the other half-shell 2b, it would be possible to block the cartridge 7 firmly, both due to the mutual fastening of the half-shells 2a and 2b and due to the interference between the toggle lever and the cartridge 7.

**[0044]** Other equally valid embodiments may provide for the presence of grub screws (or regular screws) that are rigidly coupled to the surface of the half-shells 2a and 2b and engage, by screwing, respective receptacles formed in the side walls of each cartridge 7.

**[0045]** All the details may further be replaced with other technically equivalent ones.

**[0046]** In the embodiments described, individual characteristics, given in relation to specific examples, may actually be interchanged with other different characteristics that exist in other embodiments.

**[0047]** Moreover, it is noted that anything found to be already known during the patenting process is understood not to be claimed and to be the subject of a disclaimer.

**[0048]** In practice, the materials used, as well as the shapes and dimensions, may be any according to requirements without thereby abandoning the scope of the protection of the appended claims.

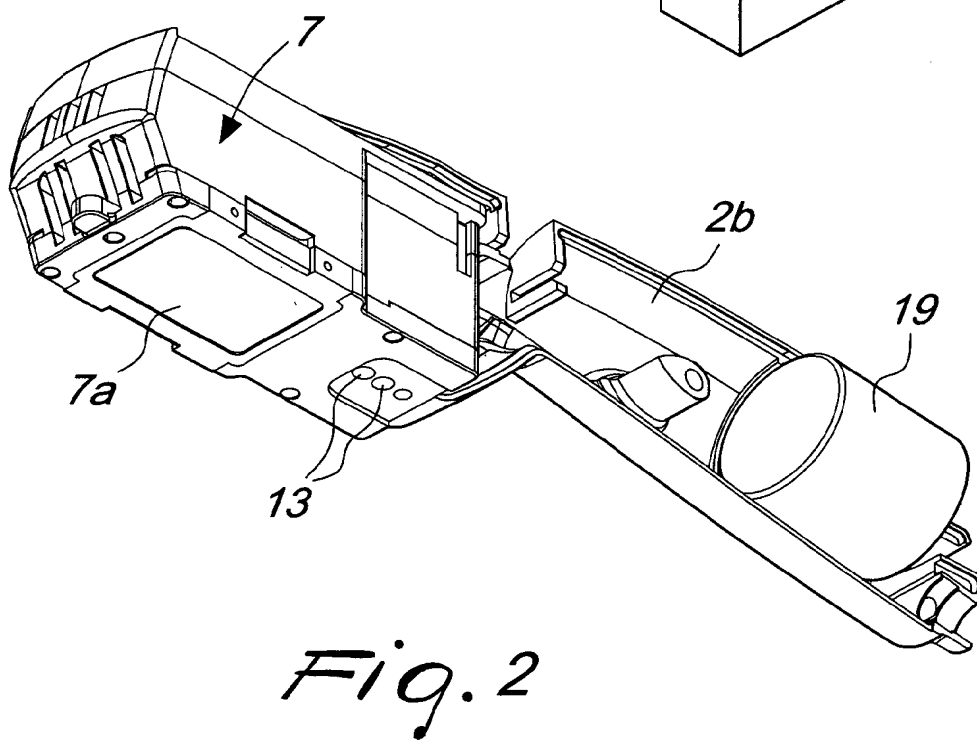
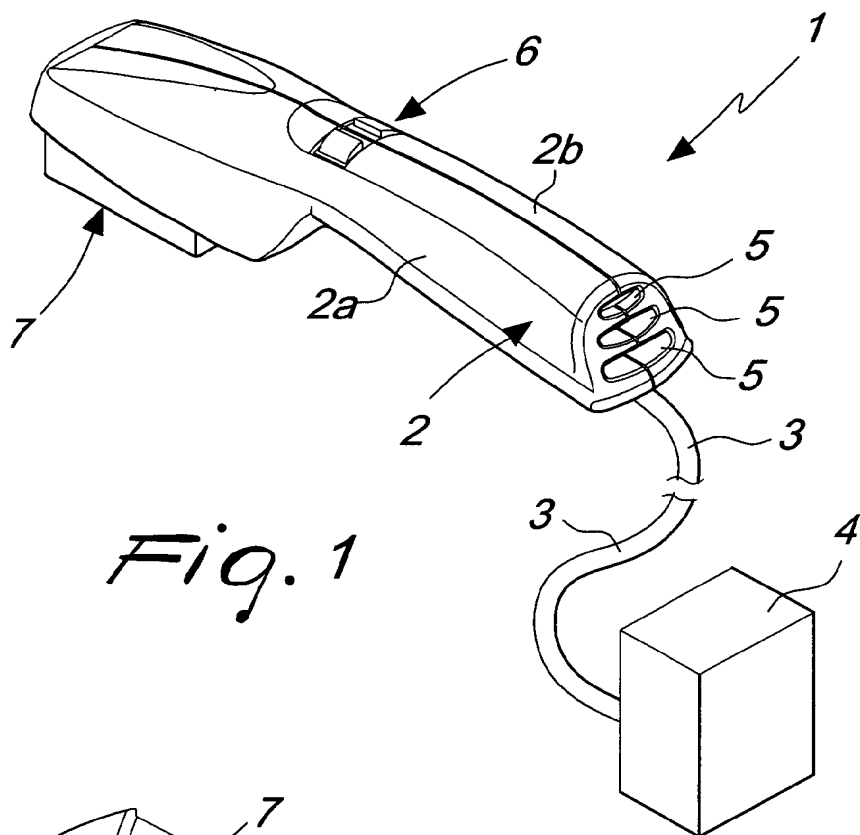
**[0049]** The disclosures in Italian Patent Application No. BO2003A000717 from which this application claims priority are incorporated herein by reference.

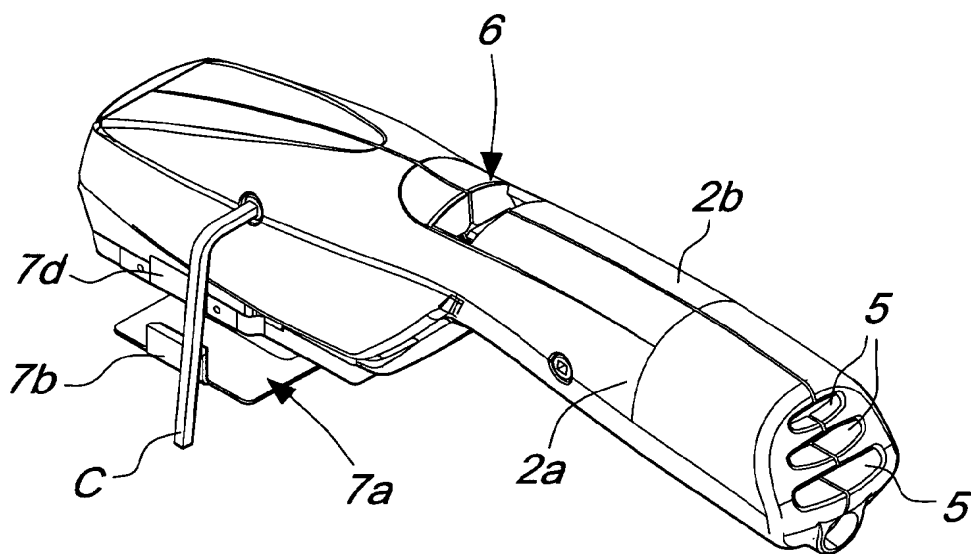
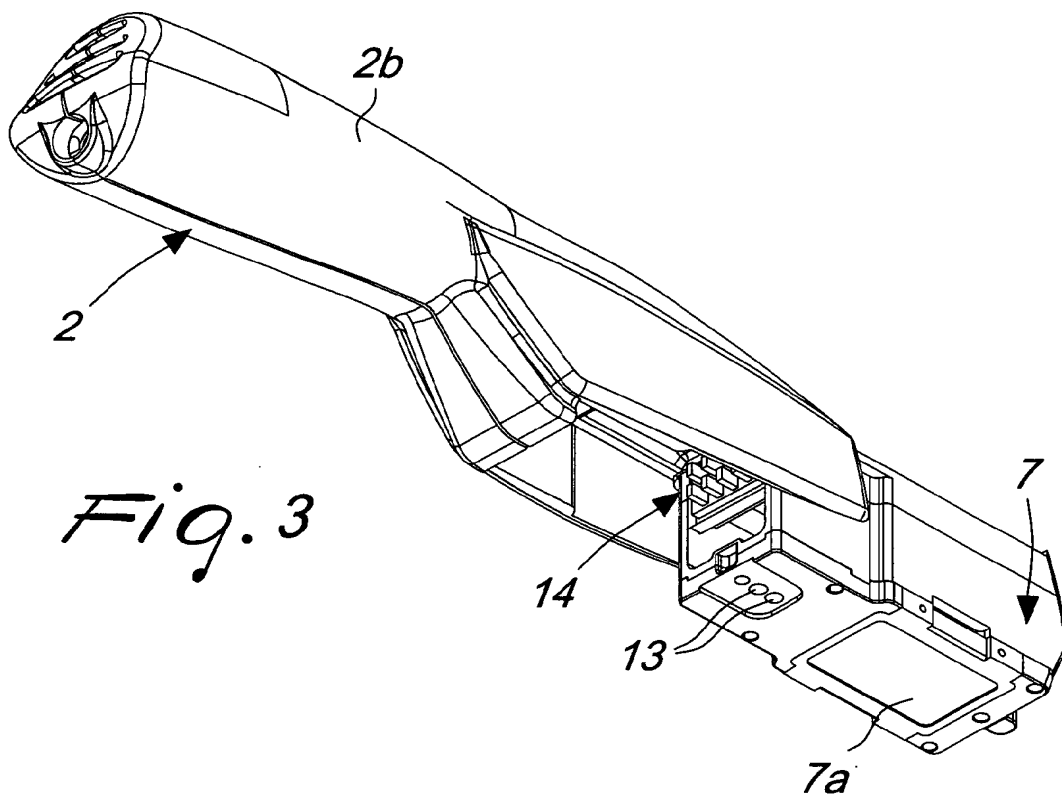
**[0050]** Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

## Claims

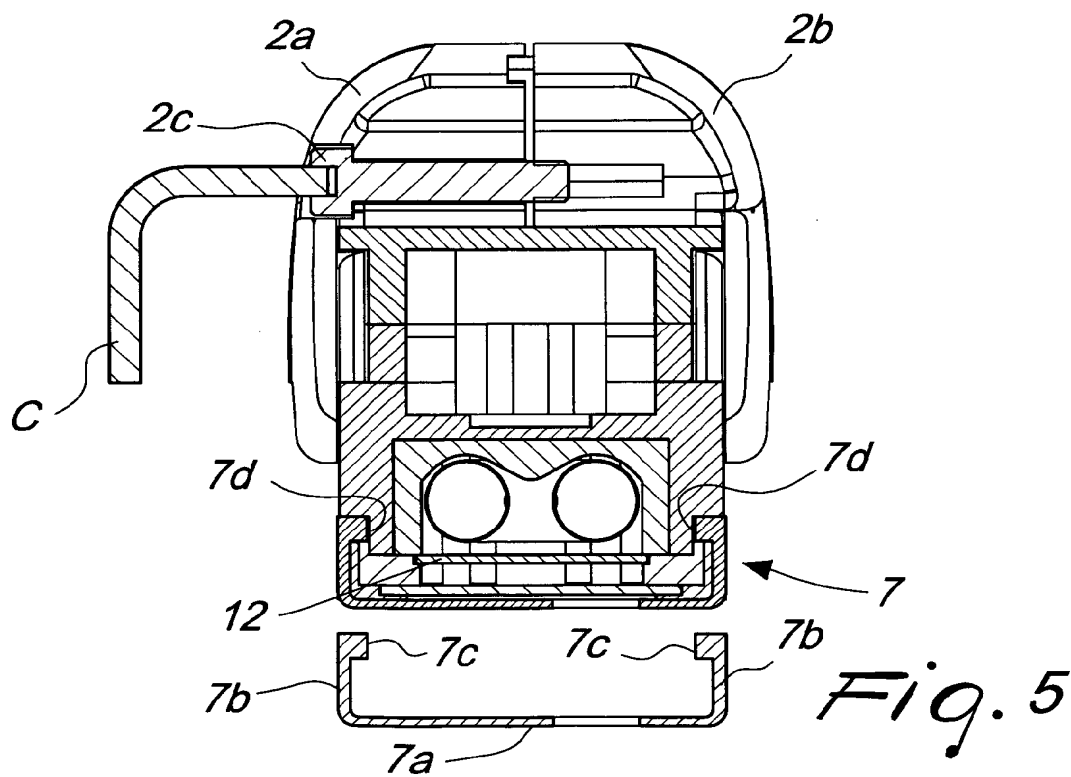
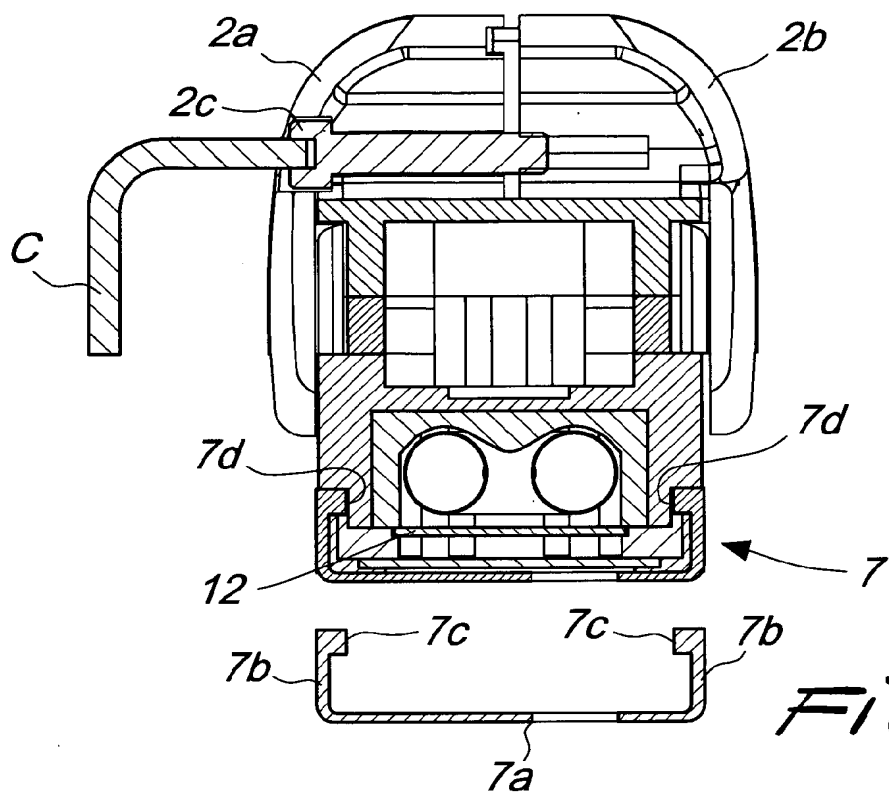
1. A light irradiation unit, of the type that comprises a control processor (4) and a handpiece (2), which is connected electrically to said processor (4) and is

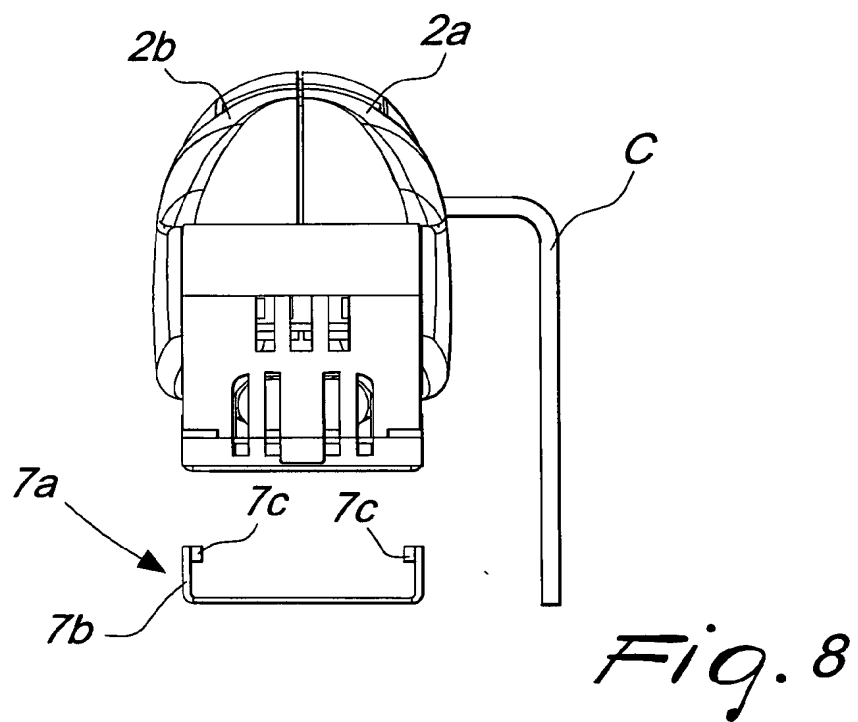
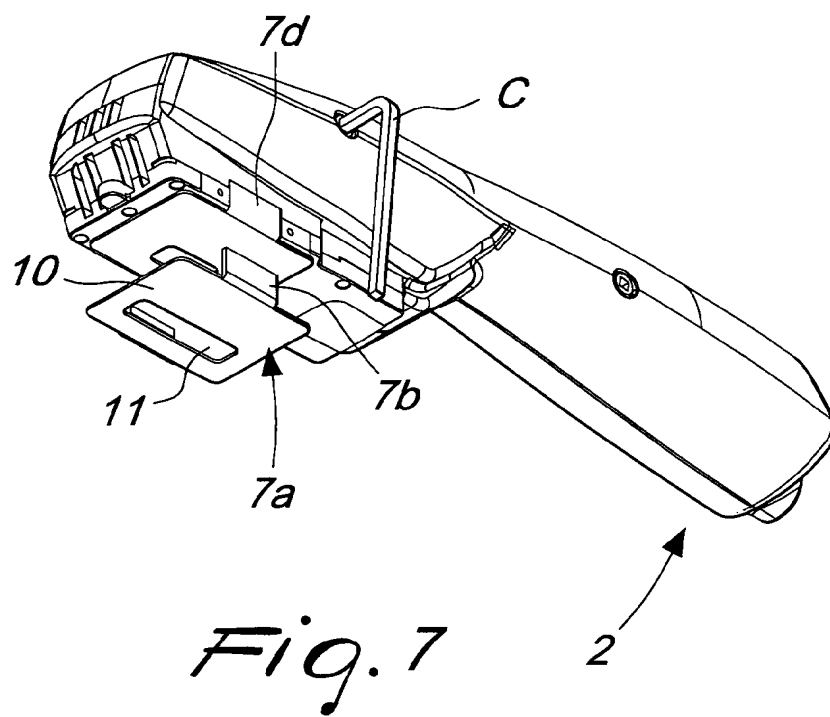
- provided with a light source (17) and with at least one filter (12) that is interposed between said source (17) and a front opening of said handpiece (2) for the exit of the light, **characterized in that** said handpiece (2) is enclosed by two symmetric half-shells (2a, 2b), which are mutually coupled so as to constitute a chamber; **in that** said light source (17) and said filter (12) are fitted on a cartridge (7) that can be inserted in a portion of said chamber, said cartridge (7) being associable within said portion by way of locking means, and **in that** a plate (7a) of a material that is permeable to light radiation is fitted on said cartridge (7) proximate to said filter (12) and parallel thereto.
2. The unit according to claim 1, **characterized in that** said cartridge (7) is shaped substantially like a parallelepiped and is provided with front channels (8) and rear channels (8a) for the passage of air and with a plurality of electrical contacts (14) for connection to the handpiece (2).
  3. The unit according to claim 1, **characterized in that** said locking means are the walls of said half-shells (2a, 2b), which can be fastened to each other by means of an appropriate wrench (C), clamping said cartridge (7) within said portion of said chamber.
  4. The unit according to claim 1, **characterized in that** said locking means are threaded elements (2c), which are accommodated within through holes of said half-shells (2a, 2b) and can be turned by means of an appropriate wrench (C), fastening said cartridge (7) within said portion of said chamber.
  5. The unit according to claim 1, **characterized in that** said locking means are constituted by at least one toggle lever, which is articulated on one of said half-shells (2a), engages in a protrusion of the other half-shell (2b), and is suitable to hinder the exit of said cartridge (7) from said portion of said chamber.
  6. The unit according to claim 1, **characterized in that** said plate (7a) that is permeable to light radiation has two perimetric bands (7b), which are arranged at right angles thereto and are provided with end protrusions (7c) for anchoring to the side walls of said cartridge (7).
  7. The unit according to claims 1 and 6, **characterized in that** said cartridge (7) has, along its side walls, proximate to the open surface, from which said filter (12) can be accessed, two longitudinal grooves (7c), which are suitable to accommodate stably said protrusions (7b) of said plate (7).
  8. The unit according to claim 1, **characterized in that** said plate (7) is made of glassy material.
  9. The unit according to claim 1 and as an alternative to claim 8, **characterized in that** said plate (7) is made of crystalline material.
  10. The unit according to claim 1, **characterized in that** said plate (7) is made of polymeric material.
  11. The unit according to one or more of the preceding claims, **characterized in that** the emitted radiation has wavelengths comprised between 1 and 2000 nanometers.
  12. The unit according to one or more of the preceding claims, **characterized in that** inside said handpiece (1) and said cartridge (7), all the components are mounted so that they are mutually spaced in order to facilitate convection for cooling.
  13. The unit according to one or more of the preceding claims, **characterized in that** said handpiece (1) comprises a small electric motor, which drives a fan (19) that is installed upstream of a duct arranged inside the handpiece (2), which is connected to the outside at the front and at the rear of said handpiece (2); said motor, said fan (19) and said duct being suitable to cool said light source (17) installed in said cartridge (7).
  14. The unit according to one or more of the preceding claims, **characterized in that** said handpiece (2) comprises a hydraulic circuit, which is constituted by a continuous channel that is distributed along the handpiece and is connected, by means of a delivery tube and a return tube, to a refrigeration unit.
  15. The unit according to claim 1, **characterized in that** said light source (17) affects a rectangular skin treatment area which has an area of approximately 5 and 3 centimeters.
  16. The unit according to claim 1, **characterized in that** said cartridge (7) containing said light source (17) is provided with masks (10) for reducing the treatment area, which can be superimposed on said plate (7a).
  17. The unit according to claim 16, **characterized in that** said masks (10) are plates made of non-transparent material, which are provided with small openings and are installed on respective sliders along the lateral surfaces of the cartridge (7) that contains the light source (17), said masks being able to perform a translational motion and a rotation from a configuration in which they are parallel and proximate to said lateral surfaces to a configuration in which they are interposed between said light source (17) and the skin, reducing the illuminated area.

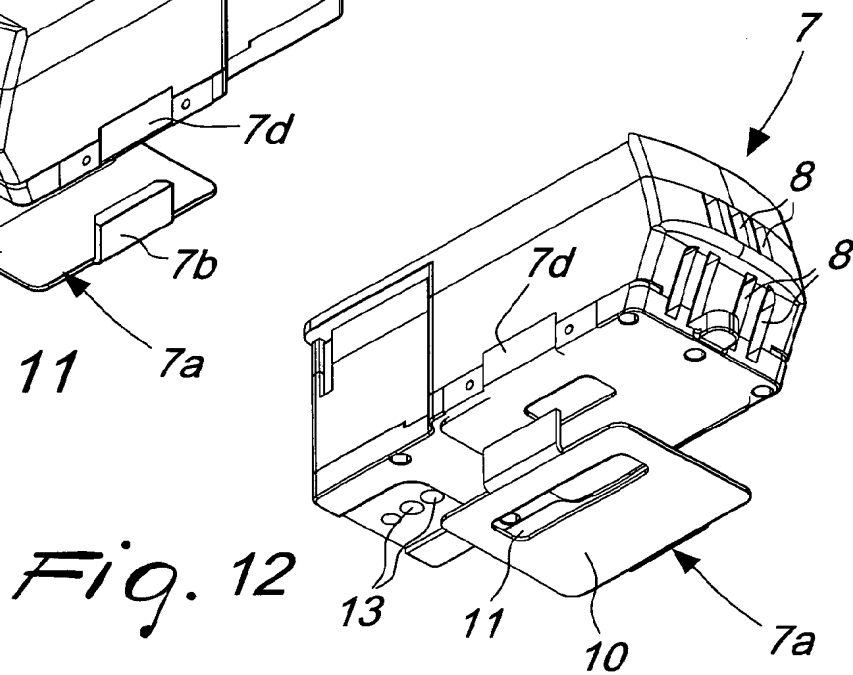
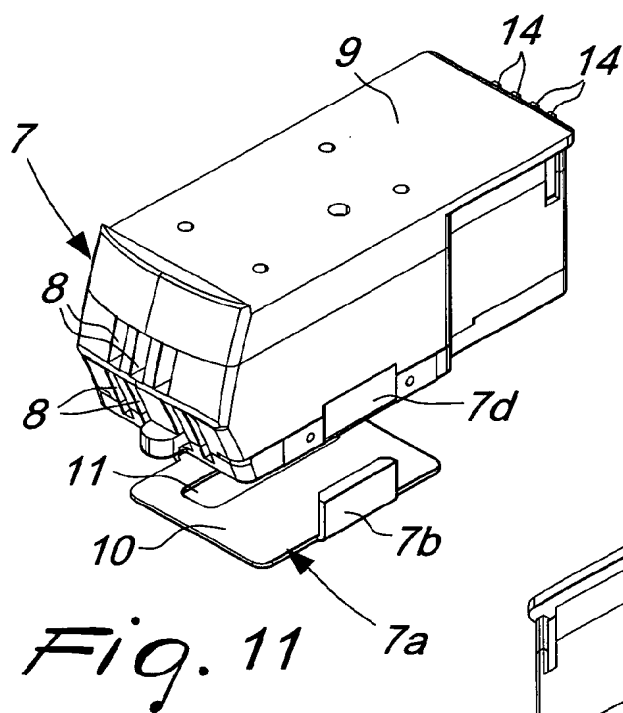
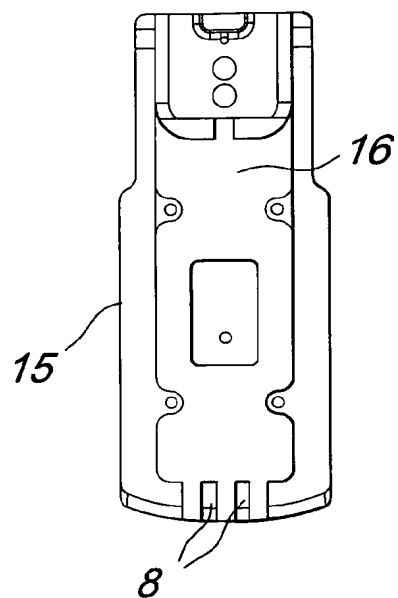
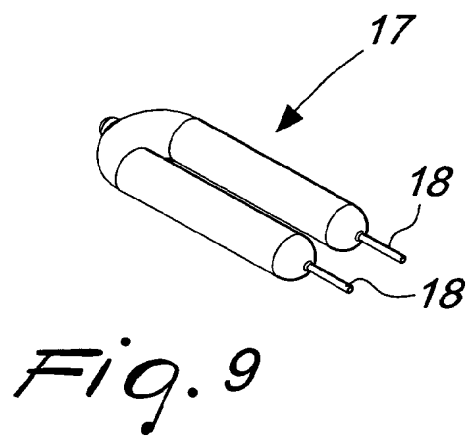




*Fig. 6*











European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number  
EP 04 02 5840

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	WO 03/043514 A (GENERAL PROJECT S.R.L; NALDONI, MORENO) 30 May 2003 (2003-05-30) * the whole document * * page 5, line 2 - page 6, line 19 * -----	1	A61B18/20
A	GB 2 369 057 A (* LYNTON LASERS LIMITED) 22 May 2002 (2002-05-22) * abstract * -----	1	
A	WO 02/082866 A (EL.EN S.P.A; MODI, STEFANO) 17 October 2002 (2002-10-17) * claim 1 * -----	1	
T	WO 2004/096072 A (O.I. OESSE INTERNATIONAL S.R.L; MAGRI, MICHAEL) 11 November 2004 (2004-11-11) * the whole document * -----	1	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B
The present search report has been drawn up for all claims			
Place of search <b>The Hague</b>		Date of completion of the search <b>18 February 2005</b>	Examiner <b>Petter, E</b>
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			

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**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 02 5840

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
The members are as contained in the European Patent Office EDP file on  
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18-02-2005

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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(12)

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## (54) Apparatus for vacuum-assisted light-based treatments of the skin

(57) A method and apparatus are disclosed for enhancing the absorption of light in targeted skin structures. A vacuum chamber having a clear transmitting element transparent to intense pulsed light on its proximate end and an aperture on its distal end is placed on a skin target. After applying a vacuum to the vacuum chamber and modulating the applied vacuum, the concentration of blood and/or blood vessels is increased within a pre-

termined depth below the skin surface of the skin target. Optical energy associated with light directed in a direction substantially normal to a skin surface adjoining the skin target is absorbed within the predetermined depth. The apparatus is suitable for treating vascular lesions with a reduced treatment energy density level and pain sensation than that of the prior art and for evacuating condensed vapors produced during the cooling of skin prior to firing the light with a controlled delay.

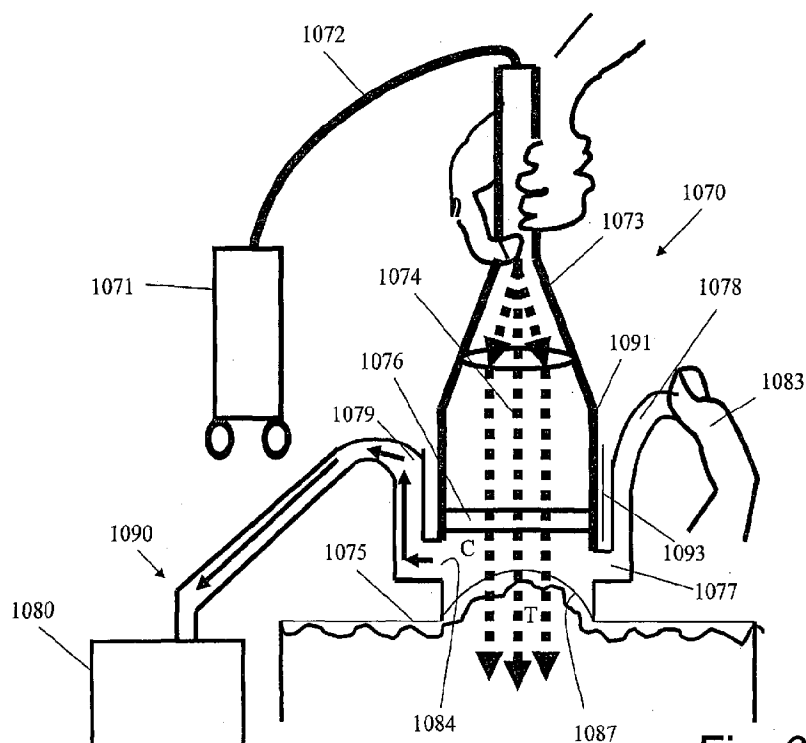


Fig. 6

**Description**

[0001] This application claims priority from US Patent Application 11/057,542 (filed February 14, 2005), which claims priority from Israeli Patent Application No. 160510 (filed on February 22, 2004), and from US Patent Application 10/498,382 (filed June 10, 2004), which is a Continuation-In-Part of PCT/IL02/00635 (filed on August 2, 2002), which is derived from IL 147009 (filed on December 10, 2001) and from IL 150094 (filed on June 6, 2002).

**Field of the Invention**

[0002] The present invention is related to the field of light-based skin treatments. More specifically, the invention is related to the utilization of light sources for the non-invasive treatment of skin disorders under the skin surface, whereby light is selectively absorbed by hair shafts, blood vessels, or collagen bundles, for the treatment or destruction of unwanted hairs, of blood vessels, or of other skin disorders.

**Background of the Invention**

[0003] Prior art very high intensity, short duration pulsed light systems which operate in the visible part of the spectrum, such as flashlamps or intense pulsed lasers are currently used in aesthetic treatments by one of two known ways: a) Applying the light to the skin without applying any pressure on the treatment zone, so as not to interfere with the natural absorption properties of skin; and b) Applying pressure onto the skin by means of the exit window of the treatment device in contact with the skin, thereby expelling blood from the light path within the skin and enabling better transmission of the light to a skin target in cases where the spectral lines of the treatment light source match absorption lines of the blood.

[0004] The major applications of intense pulsed light or intense pulsed laser systems are hair removal, coagulation of blood vessels for e.g. port wine stains, telangectasia, spider veins and leg veins, multiple heating of blood vessels for e.g. rosacea, treatment of pigmented skin such as erasure of black stains and sun stains or tattoo removal, and removal of fine wrinkles by heating the tissue around the wrinkles, normally referred to as photorejuvenation.

[0005] US Patent Nos. 5,226,907, 5,059,192, 5,879,346, 5,066,293, 4,976,709, 6,120,497, 6,120,497, 5,626,631, 5,344,418, 5,885,773, 5,964,749, 6,214,034 and 6,273,884 describe various laser and non-coherent intense pulsed light systems. These prior art light systems are not intended to increase the natural absorption of the skin.

[0006] Applying a vacuum to the skin is a known prior art procedure, e.g. for the treatment of cellulites, which complements massaging the skin. Such a procedure produces a flow of lymphatic fluids so that toxic substances may be released from the tissue. As the vacuum is applied, a skin fold is formed. The skin fold is raised above the surrounding skin surface, and the movement of a handheld suction device across the raised skin performs the massage. The suction device is moved in a specific direction relative to the lymphatic vessels, to allow lymphatic fluids to flow in their natural flow direction. The lymphatic valve in each lymphatic vessel prevents the flow of lymphatic fluid in the opposite direction, if the suction device were moved incorrectly. Liquids generally accumulate if movement is not imparted to the raised skin. The massage, which is generally carried out by means of motorized or hand driven wheels or balls, draws lymphatic fluids from cellulite in the adipose subcutaneous region and other deep skin areas, the depth being approximately 5-10 mm below the dermis.

[0007] US Patent No. 5,961,475 discloses a massaging device with which negative pressure is applied to the skin together during massaging. A similar massaging device which incorporates a radio frequency (RF) source for the improvement of lymphatic flow by slightly heating the adipose tissue is described in US Patent No. 6,662,054. Some massaging systems, such as those produced by Deka and Cynosure, add a low power, continuous working (CW) light source of approximately 0.1-2 W/cm<sup>2</sup>, in order to provide deep heating of the adipose tissue by approximately 1-3°C degrees and to enhance lymphatic circulation. The light sources associated with vacuum lymphatic massage devices are incapable of inducing blood vessel coagulation due to their low power. Also, prior art vacuum lymphatic massage devices are adapted to induce skin protrusion or to produce a skin fold by applying a vacuum.

[0008] Selective treatment of blood vessels by absorption of intense pulsed laser radiation is possible with Dye lasers operating at 585 nm, as well as with other types of lasers. Photorejuvenation has also been performed with Diode lasers in the near infrared spectral band of 800-980 nm and with Nd:YAG lasers having a frequency of approximately 1064 nm with limited success. The light emitted by such lasers is not well absorbed by tiny blood vessels or by the adjoining liquid. Broadband non-coherent intense pulsed light systems are also utilized for photorejuvenation with some success, although requiring more than 10 repeated treatments. The heat which is absorbed by the blood vessels, as a result of the light emitted by the intense short pulse devices, is transferred to adjacent collagen bundles.

[0009] The absorption of pulsed Diode and Nd:YAG laser beams by blood vessels is lower than the absorption of pulsed Dye laser beam. In order to compensate for limited photorejuvenation with red and infrared intense pulsed light and laser systems, a very high energy density as high as 30-60 J/cm<sup>2</sup> needs to be generated. At such an energy density, the melanin-rich epidermis, particularly in dark skin, is damaged if not chilled. A method to reduce the energy density of

intense pulsed lasers or non-coherent intense pulsed light sources which operate in the visible or the near infrared regions of the spectrum will therefore be beneficial.

**[0010]** Pulsed dye lasers operating in the yellow spectral band of approximately 585-600 nm, which is much better absorbed by blood vessels, are also utilized for the smoothing of fine wrinkles. The energy density of light emitted by Dye lasers, which is approximately 3-5 J/cm<sup>2</sup>, is much lower than that of light emitted by other lasers. However, the pulse durations of light emitted by Dye lasers are very short, close to 1 microsecond, and therefore risk the epidermis in darker skin. Treatments of wrinkles with Dye lasers are slow, due to the low concentration of absorbing blood vessels, as manifested by the yellow or white color of treated skin, rather than red or pink characteristic of skin having a high concentration of blood vessels. Due to the low energy density of light emitted by Dye lasers, as many as 10 treatments may be necessary. A method to reduce the energy density of light generated by Dye lasers, or to reduce the number of required treatments at currently used energy density levels, for the treatment of fine wrinkles, would be beneficial.

**[0011]** Pulsed Dye lasers operating at 585 nm are also utilized for the treatment of vascular lesions such as port wine stains or telangiectasia or for the treatment of spider veins. The energy density of the emitted light is approximately 10-15 J/cm<sup>2</sup>, and is liable to cause a burn while creating the necessary purpura. A method to reduce the energy density of light emitted by Dye lasers for the treatment of vascular lesions would be highly beneficial.

**[0012]** Hair removal has been achieved by inducing the absorption of infrared light, which is not well absorbed by melanin present in hair strands, impinging on blood vessels. More specifically, absorption of infrared light by blood vessels at the distal end of hair follicles contributes to the process of hair removal. High intensity pulsed Nd:YAG lasers, such as those produced by Altus, Deka, and Iridex, which emit light having an energy density of more than 50 J/cm<sup>2</sup>, are used for hair removal. The light penetration is deep, and is often greater than 6 millimeters. Some intense pulsed light or pulsed laser systems, such as that produced by Syneron, used for hair removal or photorejuvenation also employ an RF source for further absorption of energy within the skin.

**[0013]** The evacuation of smoke or vapor, which is produced following the impingement of monochromatic light on a skin target, from the gap between the distal end window of a laser system and the skin target, is carried out in conjunction with prior art ablative laser systems such as Co<sub>2</sub>, Erbium or Excimer laser systems. The produced smoke or vapor is usually purged by the introduction of external fresh air at greater than atmospheric pressure.

**[0014]** Coagulative lasers such as pulsed dye lasers or pulsed Nd:YAG lasers, which treat vascular lesions under the skin surface without ablating the skin surface, are generally not provided with an evacuation chamber which produces subatmospheric pressure over a skin target.

**[0015]** Some prior art intense pulsed laser systems, which operate in the visible and near infrared region of the spectrum and treat lesions under the skin surface, e.g. vascular lesions, with pulsed dye laser systems or pulsed Nd:YAG lasers, employ a skin chilling system. Humidity generally condenses on the distal window, due to the use of a skin chilling system. The humidity is not caused by the skin treatment, but rather by the low temperature of the distal window. It would be advantageous to evacuate the condensed vapors from the distal window of the laser system prior to the next firing of the laser.

**[0016]** US Patent Nos. 5,595,568 and 5,735,844 describe a coherent laser system for hair removal whereby pressure is applied to the skin by a transparent contact device in contact therewith, in order to expel blood present in blood vessels from a treatment zone. In this approach blood absorption decreases in order to increase subcutaneous light penetration.

**[0017]** US Patent Nos. 5,630,811 and 5,853,407 also describe a coherent laser system for hair removal which restricts local blood flow, in order to reduce damage to the skin tissue surrounding the hairs. Local tissue structures are flattened by applying positive pressure or negative pressure to the skin. The treatment beam is limited to only 5 mm. The treatment beam is not suitable for a larger treatment spot per pulse of approximately 40 mm. Blood expulsion is not uniform and not instantaneous for such large treatment spots, and therefore blood may remain in the skin tissue after the laser beam has been fired. Also, a large-diameter treatment device may not be easily repositioned to another treatment site, due to the relatively high lifting force needed when negative pressure is applied to the skin. Furthermore, this laser system does not provide any means for preventing gel obstruction when negative pressure is applied to the skin. Although applying a flattening positive pressure or negative pressure to a small-diameter treatment area enhances hair removal, the treatment of vascular lesions is not improved since fewer blood vessels are present within the treatment area due to the blood expulsion. A need therefore exists for a vacuum-assisted device that can alternatively reduce or increase the blood volume fraction within a skin target.

**[0018]** The light-based non-ablative treatment of hair or of vascular lesions is often very painful, particularly during the treatment of dark and thick unwanted hairs which may appear in a bikini line, on the legs, or on the back. A pain sensation is felt with almost all types of light based devices for hair removal, including intense pulsed light sources and lasers.

**[0019]** The aforementioned prior art efforts to expel blood vessels help in some cases to avoid unnecessary damage to skin structures which are not intended to be treated, such as unnecessary coagulation of blood vessels during a hair removal treatment, while increasing hair removal efficacy. The reduction in damage to skin structures does not alleviate the immediate pain sensed during a treatment, but rather, the expulsion of blood causes a higher exposure of the hair

shaft to a treatment pulse of light, resulting in a higher hair follicle temperature and a correspondingly higher level of acute pain due to excessive heating of the nerves which surround the hair shafts. Furthermore, the expelling of blood from one skin area increases the fractional blood volume in adjacent areas, causing a risk of thermal damage if the treatment light diffuses to the adjacent blood rich zone. It is well known to light-based hair removal practitioners that acute pain is felt during the treatment when hairy areas, particularly characterized by dark thick hair, are impinged by the treatment beam, whereas firing the light beam on a hairless area is substantially painless. It can therefore be concluded that the pain which is sensed during a hair removal treatment is generated by nerves surrounding the hair shafts, and not by nerves distributed in other areas of the skin. There is therefore a need for an improved apparatus for pain reduction without having to reduce the treatment energy density.

**[0020]** Two types of a pain sensation caused by light-based aesthetic treatments are recognizable: immediate sharp pain and long term milder pain. The immediate sharp pain is felt during each treatment pulse and increases to an intolerable sensation after a few shots, necessitating a patient to rest during a long delay before continuing the treatment. The treatment rate, particularly for large areas such as on the legs, is therefore considerably reduced. Depending on his pain tolerance, the patient may even decide not to continue the treatment. The sharp pain is caused by the exposure of treatment light to nerve endings located in the epidermis and dermis, by sensory receptors of hair shafts located deep in the dermis, or by the stimulation of nerves surrounding the hair bulbs as the hair shafts are being heated during the treatment, often at a temperature of approximately 70°C.

**[0021]** The less acute, long term milder pain is caused by the accumulative increase of skin temperature following treatment, e.g. during a period ranging from 10 minutes to a day after treatment, which is approximately 3 to 5 °C above body temperature. The increase in skin temperature may induce redness and edema, causing pain, depending on the hair density and the fractional blood volume within the adjoining tissue. The application of a cold gauze immediately after the treatment usually helps to avoid the post-treatment pain.

**[0022]** The most common prior art method for alleviating or preventing the immediate sharp pain caused by the non-ablative treatment of hair or of vascular lesions with intense pulsed light is the application of EMLA cream produced by AstraZeneca Canada Inc. Such cream is a topical anesthetic applied to the skin approximately 30-60 minutes before a treatment, which numbs the skin and decreases the sensation of pain. This prior art method is generally impractical due to the long and inconvenient waiting time between the application of the EMLA cream and the treatment. Since health professionals prefer to maximize the number of patients to be treated during a given time period, the health clinic must provide a large waiting room for those patients that are waiting to be treated by intense pulsed light following the application of the EMLA cream.

**[0023]** Pain caused by the non-ablative treatment of hair or of vascular lesions may also be alleviated or prevented by reducing the energy density of the intense pulsed light. Energy density reduction, however, compromises the treatment quality, and therefore is an unacceptable solution, particularly due the relatively high cost of treatment.

**[0024]** US Patent Nos. 6,264,649 and 6,530,920 disclose a cooling head for a skin treatment laser and a method to reduce or eliminate pain during laser ablative treatments of the skin by cooling the skin surrounding the treatment area. The pain is associated with the ablation or burning of a skin surface during skin resurfacing. An extraction port of the cooling head enables removal of debris material, such as smoke produced by the skin treatment laser, from the treatment area and for connection to a vacuum source. Evacuated vapor such as smoke is replaced by fresh and clean air.

**[0025]** With respect to prior art smoke evacuation devices, a significant subatmospheric pressure is generally not generated over a skin surface due to the introduction of fresh atmospheric pressure air. If subatmospheric pressure were maintained over a skin surface, the treatment handpiece would be prevented from being lifted and displaced from one skin site to another during the treatment process. Additionally, prior art smoke evacuation devices are not associated with non-ablative lasers, such as a long-pulse Nd:YAG laser, which treat tissue only under the skin surface and do not produce smoke resulting from the vaporization of the skin surface. Furthermore, the application of heat releasing gel onto a skin target is not conducive for the ablation of a skin surface or for the subsequent evacuation of debris material since the gel forms a barrier between the skin surface and the surrounding air.

**[0026]** Current laser and IPL skin treatment systems utilize chilling means. However, pain is still noticeable.

**[0027]** A need therefore exists for alleviating the resulting pain caused by the treatment of unwanted hair, unwanted wrinkles or vascular lesions by intense pulsed light or intense pulsed laser systems, without reducing the light source intensity, without applying a topical anesthetic, and without using a chiller as means to reduce pain.

**[0028]** It is an object of the present invention to provide a method and apparatus for the treatment of subcutaneous lesions, such as vascular lesions, by a non-ablative, high intensity pulsed laser or light system operating at wavelengths shorter than 1800 nm which does not damage the surface of the skin or the epidermis.

**[0029]** It is an object of the present invention to provide a method and apparatus for controlling the depth of subcutaneous light absorption.

**[0030]** It is an object of the present invention to provide a method and apparatus for increasing the absorption of light which impinges a skin target by increasing the concentration of blood vessels thereat.

**[0031]** It is an additional object of the present invention to provide a method and apparatus by which the energy density

level of intense pulsed light that is suitable for hair removal, fine wrinkle removal, including removal of wrinkles around the eyes and in the vicinity of the hands or the neck, and the treatment of port wine stain or rosacea may be reduced relative to that of the prior art.

**[0032]** It is an additional object of the present invention to provide a method and apparatus by which the number of required treatments for hair removal, fine wrinkle removal, including removal of wrinkles around the eyes and in the vicinity of the hands or the neck, and the treatment of port wine stain or rosacea at currently used energy density levels may be reduced relative to that of the prior art.

**[0033]** It is yet an additional object of the present invention to provide a method and apparatus for repeated evacuation, prior to the firing of a subsequent light pulse, of vapors which condense on the distal window due to the chilling of laser treated skin.

**[0034]** It is yet an additional object of the present invention to provide a method and apparatus for alleviating the resulting pain caused by the treatment of unwanted hair, unwanted wrinkles or vascular lesions by intense pulsed light or intense pulsed laser systems, without reducing the light source intensity, without applying a topical anesthetic, and without relying on skin chilling for pain reduction.

**[0035]** It is yet an additional object of the present invention to provide a method and apparatus for speedy repositioning of a vacuum-assisted, non-ablative light-based treatment handpiece from one site to another.

**[0036]** It is yet an additional object of the present invention to provide a method and apparatus for a vacuum-assisted, light-based skin treatment which is conducive for the application of a heat releasing gel onto a skin surface, without resulting in obstruction of vacuum generating apparatus.

**[0037]** It is a further object of the present invention to provide an apparatus for vacuum-assisted, light-based treatment which can be held by one hand while a light treatment handpiece is held by the other hand.

**[0038]** Other objects and advantages of the invention will become apparent as the description proceeds.

### **Summary of the Invention**

**[0039]** The present invention is directed to apparatus for vacuum-assisted light-based skin treatments. The apparatus comprises a vacuum chamber which is transparent or translucent to intense pulsed monochromatic or non-coherent light directed to a skin target. A vacuum is applied to said vacuum chamber, whereby said skin target is drawn to said vacuum chamber. The efficacy and utility of the apparatus are achieved by employing the apparatus in two modes: (a) in a vacuum applying mode wherein a high vacuum level ranging from 0-1 atmospheres is attained and (b) in a vacuum release mode upon deactivation of the light source and of the vacuum pump after optical energy associated with the directed light has been absorbed within a predetermined depth under the skin surface, wherein atmospheric air is introduced to the vacuum chamber so that the vacuum chamber may be speedily repositioned to another skin target.

**[0040]** In one embodiment of the invention, the apparatus comprises:

- a) a non-ablative intense pulsed monochromatic or non-coherent light source;
- b) a vacuum chamber placeable on a skin target which has an opening on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to light generated by said source and directed to said skin target;
- c) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said opening; and
- d) means for preventing influx of air into vacuum chamber during a vacuum applying mode.

**[0041]** As referred to herein, "distal" is defined as a direction towards the exit of the light source and "proximate" is defined as a direction opposite from a distal direction.

**[0042]** The terms "evacuation chamber" and "vacuum chamber" as referred to herein are interchangeable.

**[0043]** The vacuum chamber is advantageously one-hand graspable by means of a handle connected thereto so that the vacuum chamber can be held by one hand while a light treatment handpiece is held by the other hand.

**[0044]** Preferably-

- a) the vacuum applying means comprises a vacuum pump and at least one control valve;
- b) the wavelength of the light ranges from 400 to 1800 nm;
- c) the pulse duration of the light ranges from 10 nanoseconds to 900 msec;
- d) the energy density of the light ranges from approximately 2 to approximately 150 J/cm<sup>2</sup>;
- e) the level of applied vacuum within the vacuum chamber ranges from approximately 0 to approximately 1 atmosphere;
- f) the light source is selected from the group of Dye laser, Nd:YAG laser, Diode laser, light emitting diode, Alexandrite laser, Ruby laser, Nd:YAG frequency doubled laser, Nd:Glass laser, a non-coherent intense pulse light source, and

a non-coherent intense pulse light source combined with an RF source;

g) the light is suitable for hair removal, collagen contraction, photorejuvenation, treatment of vascular lesions, treatment of sebaceous or sweat glands, treatment of warts, treatment of pigmented lesions, treatment of damaged collagen, treatment of acne, treatment of warts, treatment of keloids, treatment of sweat glands, and treatment of psoriasis;

h) the light is suitable for the treatment of vascular lesions selected from the group of port wine stains, telangiectasia, rosacea, and spider veins;

i) the clear transmitting element is suitable for transmitting the light in a direction substantially normal to a skin surface adjoining said skin target;

j) the clear transmitting element is separated from the adjoining skin surface by a gap ranging from 0.5 to 50 mm, and preferably approximately 2 mm;

k) the treatment spot per pulse is greater than 5 mm, and preferably between 15 to 50 mm;

l) the influx of air into vacuum chamber during a vacuum applying mode is prevented by means of a control valve and control circuitry or by means of manual occlusion of a vacuum chamber conduit;

m) the ratio of the maximum length to maximum width of the aperture formed on the distal end of the vacuum chamber ranges from approximately 1 to 4;

n) the vacuum chamber has at least one suction opening, the vacuum being applied to the vacuum chamber via said at least one suction opening;

o) the vacuum chamber is U-shaped; and

p) the vacuum chamber is provided with a rim for sealing the peripheral contact area between the skin surface adjoining the skin target and the vacuum chamber wall.

**[0045]** Preferably, the apparatus further comprises control means for controlling operation of the vacuum pump, the at least one control valve, and the light source. The control means is selected from the group of electronic means, pneumatic means, electrical means, and optical means. The control means may be actuated by means of a finger depressable button, which is positioned on a light treatment handpiece.

**[0046]** In one aspect, the control means is suitable for firing the light source after a first predetermined delay, e.g. from approximately 0.5 sec to approximately 4 seconds, following operation of the vacuum pump.

**[0047]** In one aspect, the control means is suitable for firing the light source after a predetermined delay following opening of the at least one control valve.

**[0048]** In one aspect, the control means is suitable for increasing the pressure in the vacuum chamber to atmospheric pressure following deactivation of the light source, to allow for effortless repositioning of the vacuum chamber to a second skin target. The increase in vacuum chamber pressure may be triggered by means of a light detector which transmits a signal to the control means upon sensing a significant decrease in optical energy generated by the light source or may be effected after a second predetermined delay, following deactivation of the light source.

**[0049]** In one aspect, the control means is suitable for verifying that a desired energy density level of the light is being directed to the skin target and for deactivating the light source if the energy density level is significantly larger than said desired level.

**[0050]** In one aspect, the vacuum chamber is connected to, or integrally formed with, a proximately disposed handpiece through which light propagates towards the skin target. The vacuum chamber has a proximate cover formed with an aperture, said cover being attachable or releasably attachable to a handpiece such as a light guide having an integral clear transmitting element.

**[0051]** In one aspect, the vacuum pump is an air pump.

**[0052]** In one aspect, the vacuum pump is a peristaltic pump for drawing air and gel from the interior of the vacuum chamber via a hose connected to a conduit in communication with the interior of the vacuum chamber.

**[0053]** The hose provides indication means that the skin target has undergone a light-based treatment by means of gel which is discharged from an end of the hose onto a skin surface during a vacuum applying mode.

**[0054]** In one aspect, the apparatus further comprises means to stabilize the vacuum chamber on a substantially non-planar skin surface.

**[0055]** In one aspect, the apparatus further comprises a skin contact detector for sensing the placement of the vacuum chamber onto the skin target and for generating a first signal to activate the vacuum pump following placement of the vacuum chamber onto the skin target.

**[0056]** In one aspect, the control valve is opened following generation of a second signal by means of a light detector which is adapted to sense termination of the light directed to the skin target, atmospheric pressure air thereby being introduced to the interior of the vacuum chamber.

**[0057]** In one aspect, the second signal is suitable for deactivating the vacuum pump.

**[0058]** In another embodiment of the invention, the apparatus further comprises an array of vacuum chambers placeable on a skin surface. The array is formed from a single sheet made of material which is transparent or translucent to



the light, said sheet being formed with a plurality of conduits for air evacuation such that each of said conduits is in communication with a corresponding vacuum chamber. The distance between adjacent vacuum chambers is sufficiently small to allow light which has diffused from the interior of each chamber to treat a skin area located underneath a corresponding conduit.

5 **[0059]** Each conduit preferably branches into first and second portions which are in communication with a vacuum pump and with a source of compressed air, respectively.

**[0060]** In one aspect, each vacuum chamber is provided with a contact detector for triggering a signal to activate the vacuum pump, two control valves to control the passage of fluid through the corresponding first and second conduits portions, respectively, and a light detector which generates a signal to introduce compressed air through the correspond-  
10 ing second conduit portion upon sensing the termination of the light directed to the skin target.

**[0061]** In one aspect, the first conduit portions are arranged such that the air from all vacuum chambers is evacuated simultaneously upon activation of the vacuum pump.

**[0062]** In another embodiment of the invention, the vacuum applying means comprises a vertically displaceable cover to which the clear transmitting element is secured and chamber walls which surround, and are of a similar shape as, said cover, a vacuum being generated within a vacuum chamber defined by the volume between said cover, said walls,  
15 and the skin target upon proximal displacement of said cover relative to said walls. The means for preventing influx into the vacuum chamber is a sealing element which is secured to the outer periphery of the cover and resiliently contacts the chamber walls.

**[0063]** In one aspect, a proximally directed force or distally directed force is generated by any means selected from the group of a plurality of solenoids, a spring assembly, and a pneumatic device, or a combination thereof, which are  
20 deployed around the periphery of the cover and connected to the walls, and is controllable so as to adjust the height of the drawn skin target relative to the adjoining skin surface. Due to their low power consumption, a 1.5 V battery may be used to energize the solenoids.

**[0064]** The apparatus preferably further comprises an aeration tube for introducing atmospheric air to the vacuum chamber during a vacuum release mode. The aeration tube is in communication with a valve which is actuated upon  
25 conclusion of a skin target treatment.

**[0065]** In one aspect, the proximally directed force is supplemented by means of a vacuum pump.

**[0066]** In another embodiment of the invention, the apparatus comprises means for preventing passage of skin cooling gel to the vacuum applying means.

**[0067]** In one aspect, the means for preventing passage of gel to the vacuum applying means comprises a trap, a first  
30 conduit through which gel and air are drawn from the vacuum chamber to said trap, a second conduit through which air is drawn from said trap to the vacuum pump, and optionally, a filter at the inlet of the first and second conduits.

**[0068]** In one aspect, the trap is suitable for the introduction therein of an ion exchange resin with which the gel is boundable.

**[0069]** In one aspect, the means for preventing passage of gel is a detachable vacuum chamber upper portion, detachment of said upper portion allowing removal of gel retained within the vacuum chamber interior. Suitable apparatus  
35 comprises an upper portion having an open central area, a clear transmitting element attached to said upper portion, vacuum chamber walls, a vacuum chamber cover perpendicular to said walls and suitably sized so as to support said upper portion, and a plurality of attachment clips pivotally connected to a corresponding vacuum chamber wall for detachably securing said upper portion to said vacuum chamber cover.

**[0070]** In one aspect, the vacuum chamber walls are coated with a hydrophobic material. Accordingly, the vacuum chamber provides indication that the skin target has undergone a light-based treatment by means of gel which falls to the skin surface during a vacuum release mode in the shape of the distal end of the vacuum chamber walls.

**[0071]** In one aspect, the at least one suction opening is sufficiently spaced above the distal end of a vacuum chamber  
45 wall and from the centerline of the vacuum chamber so as to prevent obstruction of the at least one suction opening by gel and drawn skin upon application of the vacuum.

**[0072]** In another embodiment of the invention, the apparatus further comprises means for skin cooling, said skin cooling means adapted to reduce the rate of temperature increase of the epidermis at the skin target. The level of the applied vacuum is suitable for evacuating condensed vapors which are produced within the gap between the clear  
50 transmitting element and the skin target and condense on the clear transmitting element during the cooling of skin.

**[0073]** In one aspect, the skin cooling means is a metallic plate in abutment with the vacuum chamber on the external side thereof, said plate being cooled by means of a thermoelectric cooler. The plate may be positionable on the skin surface adjoining said skin target in order to cool the lateral sides of the vacuum chamber or may be in contact with the clear transmitting element.

**[0074]** In one aspect, the skin cooling means is a polycarbonate layer transparent to the directed light which is attached to the distal face of the clear transmitting element.

**[0075]** In one aspect, the skin cooling means is a gel, a low temperature liquid or gas applied onto the skin target.

**[0076]** In another embodiment of the invention, the apparatus is suitable for controlling the depth of light absorption

by blood vessels under a skin surface, comprising:

- a) a vacuum chamber placed on a skin target which is formed with an aperture on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to intense pulsed monochromatic or non-coherent light directed to said skin target and suitable for transmitting the light in a direction substantially normal to a skin surface adjoining said skin target;
- b) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said aperture; and
- c) means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target, optical energy associated with the directed light being absorbed within said predetermined depth.

**[0077]** As referred to herein, the term "blood volume fraction" is interchangeable with "the concentration of blood and/or blood vessels within a predetermined depth below the skin surface".

**[0078]** In one embodiment, the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is a means for modulating the applied vacuum.

**[0079]** The depth under the skin surface at which optical energy is absorbed may be selected in order to thermally injure or treat predetermined skin structures located at said depth. As referred to herein, a "skin structure" is defined as any any damaged or healthy functional volume of material located under the epidermis, such as blood vessels, collagen bundles, hair shafts, hair follicles, sebaceous glands, sweat glands, adipose tissue. Depending on the blood concentration within the skin target, the light may propagate through the skin surface and upper skin layers without being absorbed thereat and then being absorbed at a skin layer corresponding to that of a predetermined skin structure. As referred to herein, the term "light" means both monochromatic and non-coherent light. The terms "light absorption" and "optical energy absorption" refer to the same physical process and are therefore interchangeable.

**[0080]** In contrast with a prior art vacuum-assisted apparatus for laser or intense pulsed light treatment wherein a sharp skin fold is produced through a slit following application of the vacuum, vacuum-assisted drawn skin by means of the apparatus of the present invention is not distorted, but rather is slightly and substantially uniformly drawn to the vacuum chamber, protruding approximately 1-2 mm from the adjoining skin surface. The maximum protrusion of the drawn skin from the adjoining skin surface is limited by a clear transmitting element defining the proximate end of the vacuum chamber. The clear transmitting element is separated from the adjoining skin surface by a gap of preferably 2 mm, and ranging from 0.5-50 mm. In one embodiment of the invention, the drawn skin abuts the clear transmitting element.

**[0081]** As referred to herein, "vacuum modulation" means adjustment of the vacuum level within, or of the frequency by which vacuum is applied to, the vacuum chamber. By properly modulating the vacuum, the blood flow rate, in a direction towards the vacuum chamber, within blood vessels at a predetermined depth below the skin surface can be controlled. As the concentration of blood and/or blood vessels is increased within the skin target, the number of light absorbing chromophores is correspondingly increased at the predetermined depth. The value of optical energy absorbance at the predetermined depth, which directly influences the efficacy of the treatment for skin disorders, is therefore increased.

**[0082]** Preferably-

- a) The wavelength of the light ranges from 400 to 1800 nm.
- b) The pulse duration of the light ranges from 10 nanoseconds to 900 msec.
- c) The energy density of the light ranges from 2 to 150 J/ cm<sup>2</sup>.
- d) The ratio of the maximum length to maximum width of the aperture formed on the distal end of the vacuum chamber ranges from approximately 1 to 4.
- e) The level of the applied vacuum within the vacuum chamber ranges from 0 to 1 atmosphere.
- f) The frequency of vacuum modulation ranges from 0.2 to 100 Hz.
- g) The light is fired after a predetermined delay following application of the vacuum.
- h) The predetermined delay ranges from approximately 10 msec to approximately 1 second.
- i) The duration of vacuum application to the vacuum chamber is less than 2 seconds.
- j) Vacuum modulation is electronically controlled.

**[0083]** In one embodiment of the invention, the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is at least one support element positioned at a skin area adjoining the skin target and having a thickness suitable for inducing an increase in the concentration of blood and/or blood vessels within said predetermined depth. The apparatus may further comprise at least one leg having a thickness considerably less than the at least one support element and positioned at the periphery of the vacuum chamber, said at least one leg being separated from an adjacent support element, the at least one support

element being adapted to urge blood expelled by said at least one leg towards the skin target.

**[0084]** The predetermined depth under the skin surface at which optical energy is absorbed is selected in order to thermally injure or treat predetermined skin structures located at said depth.

**[0085]** Due to implementation of the apparatus, the treatment energy density level for various types of treatment is significantly reduced, on the average of 50% with respect with that associated with prior art devices. The treatment energy density level is defined herein as the minimum energy density level which creates a desired change in the skin structure, such as coagulation of a blood vessel, denaturation of a collagen bundle, destruction of cells in a gland, destruction of cells in a hair follicle, destruction of unwanted lesions by means of photodynamic therapy, or any other desired effects. The following is the treatment energy density level for various types of treatment performed with use of the present invention:

a) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a dye laser unit and having a wavelength of 585 nm: 5-12 J/cm<sup>2</sup>;

b) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a diode laser unit and having a wavelength of 940 nm: 10-30 J/cm<sup>2</sup>;

c) treatment of vascular lesions with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm: 5-20 J/cm<sup>2</sup>;

d) photorejuvenation with light emitted from a dye laser unit and having a wavelength of 585 nm: 1-4 J/cm<sup>2</sup>;

e) photorejuvenation with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm: 5-20 J/cm<sup>2</sup>;

f) photorejuvenation with a combined effect of light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm and of a RF source: 10 J/cm<sup>2</sup> for both the intense pulsed non-coherent light unit and RF source;

g) hair removal with light emitted from a Nd:YAG laser unit and having a wavelength of 1604 nm: 25-35 J/cm<sup>2</sup>; and

h) Porphyrin-based photodynamic therapy with light emitting diodes delivering blue light (420 nm), orange light (585 nm), or red light (630 nm): 5-20 J/cm<sup>2</sup>.

**[0086]** The preferably further comprises a control unit for controlling operation of the vacuum applying means and light source. The control unit is also suitable for controlling operation of at least one control valve in communication with the vacuum chamber, for firing the light after a predetermined delay following application of the vacuum, and for electronically modulating the vacuum.

**[0087]** In one aspect, the apparatus further comprises a skin contact detector for sensing the placement of the vacuum chamber onto the skin target, the control unit being suitable for activating the vacuum applying means in response to a signal transmitted by said skin contact detector.

**[0088]** In one aspect, the apparatus further comprises a light detector for sensing the termination of the light directed to the skin target, the control unit being suitable for regulating a control valve in response to a signal transmitted by said light detector so as to introduce atmospheric pressure air to the interior of the vacuum chamber.

**[0089]** In one aspect, the apparatus further comprises a pulsed radio frequency (RF) source for directing suitable electromagnetic waves to the skin target. The frequency of the electromagnetic waves ranges from 0.2-10 MHz. The RF source is either a bipolar RF generator which generates alternating voltage applied to the skin surface via wires and electrodes or a monopolar RF generator with a separate ground electrode. The control unit is suitable for transmitting a first command pulse to the at least one control valve and a second command pulse to both the intense pulsed light source and RF source.

**[0090]** In one aspect, the apparatus further comprises an erythema sensor, said sensor suitable for measuring the degree of skin redness induced by the vacuum applying means. The control unit is suitable for controlling, prior to firing the light source, the energy density of the light emitted from the light source, in response to the output of the erythema sensor.

**[0091]** In one aspect, the vacuum chamber has a proximate cover formed with an aperture, said cover being attachable to a handpiece, such as a light guide, having an integral clear transmitting element.

**[0092]** In one aspect, the apparatus further comprises means for skin cooling, said skin cooling means adapted to reduce the rate of temperature increase of the epidermis at the skin target.

**[0093]** In one aspect, the apparatus further comprises means for preventing passage of skin cooling gel to the vacuum applying means.

**[0094]** In another embodiment of the invention, the apparatus is suitable for alleviating or preventing pain caused by a non-ablative light-based treatment of a targeted skin structure. Accordingly, the gap separating said the clear transmitting element from the skin surface adjoining said the skin target and the magnitude of the proximally directed force resulting from said the applied vacuum in combination are suitable for drawing said the skin target to said the vacuum chamber via the opening on the distal end of the vacuum chamber said aperture until said the skin target contacts said

the clear transmitting element; and the control means is suitable for firing the light source after the first predetermined delay, following operation of the vacuum applying means.

[0095] In one aspect, the apparatus is suitable for causing the skin target to contact the clear transmitting element for a duration equal to the first predetermined delay, whereby pain signals generated by the nervous system during the treatment of the skin structure are alleviated or prevented.

[0096] The control means is preferably suitable for controlling the vacuum level generated by the vacuum applying means, and has a plurality of finger depressable buttons, each of which being adapted to set the vacuum applying means and light source at a unique combination of operating conditions so as to generate a predetermined vacuum level within the vacuum chamber and to fire the light source after a predetermined time delay following the operation of the vacuum applying means.

[0097] In one aspect, a single light source and vacuum pump are operable in conjunction with differently configured vacuum chambers, for example a vacuum chamber that is suitable for pain alleviation or a vacuum chamber that is suitable for inducing an increase in blood concentration within a skin target. Each differently configured vacuum chamber is releasably attachable to a treatment light handpiece, e.g. by means of suitable threading or clips.

### **Brief Description of the Drawings**

[0098] In the drawings:

- Fig. 1 is a schematic drawing which illustrates the propagation of an intense pulsed laser beam from a handpiece to a skin target according to a prior art method;
- Fig. 2 is a schematic drawing which illustrates the propagation of an intense pulsed non-coherent light beam from a handpiece to a skin target according to a prior art method;
- Fig. 3 is a schematic drawing of a prior art treatment method by which pressure is applied to a skin target, in order to expel blood from those portions of blood vessels which are in the optical path of subcutaneously scattered light;
- Fig. 4 is a schematic drawing of a prior art vacuum-assisted rolling cellulite massage device;
- Fig. 5 is a schematic drawing of a prior art vacuum-assisted hair removal device adapted to reduce the blood concentration within a skin fold formed thereby, in order to illuminate two opposed sides of the skin fold and consequently remove melanin-rich hair shafts;
- Fig. 6 is a schematic drawing of apparatus in accordance with one embodiment of the present invention, employing a manually occluded U-shaped evacuation chamber;
- Fig. 7 is a schematic drawing of apparatus in accordance with another embodiment of the present invention, employing an electronically controlled evacuation chamber;
- Fig. 8 is a schematic drawing of apparatus in accordance with the present invention, employing an intense pulsed non-coherent light source;
- Fig. 9 is a schematic drawing of apparatus in accordance with the present invention, which is provided with a skin chiller;
- Fig. 10 is a drawing which schematically illustrates the effect of applying a subatmospheric pressure to a vacuum chamber in order to increase the blood concentration in skin drawn towards the vacuum chamber;
- Fig. 11 is a drawing which schematically illustrates the increased concentration of a plurality of blood vessels in a skin target following application of a vacuum to a vacuum chamber, resulting in increased redness of skin and enhanced absorption of light;
- Fig. 12 is a photograph illustrating the change in skin color following treatment of a fine wrinkle by use of a vacuum assisted handpiece in accordance with the present invention;
- Fig. 13 is a schematic drawing of another embodiment of the invention, illustrating propagation of intense pulsed light from an external light source to a transparent modulated vacuum chamber;
- Fig. 14 schematically illustrates another embodiment of the invention which employs both an intense pulsed light source and a radio frequency source, for improved coagulation of blood vessels;
- Figs. 15a and 15b schematically illustrate a vacuum chamber which is attachable to a light guide, wherein Fig. 15a illustrates the vacuum chamber prior to attachment and Fig. 15b illustrates the vacuum chamber following attachment;
- Fig. 16 is a schematic drawing of apparatus in accordance with another embodiment of the invention, which is suitable for alleviating pain during a light-based skin treatment;
- Fig. 17 is a schematic drawing of an exemplary trap, for preventing the passage of gel to a vacuum pump;
- Fig. 18 is a schematic perspective drawing of apparatus in accordance with another embodiment of the invention, illustrating a detachable upper portion of a vacuum chamber;
- Fig. 19 is a schematic drawing of an exemplary skin cooling device, which is suitable for the apparatus of Fig. 16;
- Fig. 20 is a schematic drawing of apparatus in accordance with yet another embodiment of the invention;
- Fig. 21 is a photograph of the back of a patient, illustrating the efficacy of the hair removal treatment of the invention;

- Fig. 22 schematically illustrates a vacuum chamber which is configured to induce the expulsion of blood from a skin target to a peripheral skin area;
- Fig. 23 schematically illustrates a vacuum chamber which is configured to induce blood transfer from a peripheral skin area to a skin target;
- 5 - Figs. 24A and 24B schematically illustrate the accumulation of gel as a vacuum chamber is displaced from skin area to another;
- Fig. 25 schematically illustrates a vacuum chamber to which a vacuum is applied by means of a peristaltic pump;
- Fig. 26A is a plan view of an array of vacuum chambers and Fig. 26B is a cross sectional view thereof, taken about plane A-A of Fig. 26A;
- 10 - Figs. 27A-C illustrate the production of a vacuum chamber by a vertically displaceable cover in three stages; and
- Fig. 28 is a schematic perspective view of a sapphire transmitting element that is suitable for transmitting both light and RF waves to a skin target.

#### **Detailed Description of Preferred Embodiments**

15 **[0099]** The present invention is directed to apparatus which is provided with a unit for evacuating vapors, such as condensed vapors that were produced during the chilling of skin prior to the firing of the laser unit. The evacuation unit comprises a U-shaped vacuum chamber through which monochromatic or intense pulsed light passes as it is directed to a skin target, and a vacuum pump. During operation of the vacuum pump, the vacuum level within the vacuum chamber

20 is increased by occluding a conduit of the vacuum chamber e.g. by a finger of the operator. As vacuum is applied to the skin target, skin is drawn toward the vacuum chamber and the concentration of blood vessels in the vicinity of the target increases. The added concentration of blood vessels increases the absorption of light within the tissue, and therefore facilitates treatment of a skin disorder.

25 **[0100]** Fig. 1 illustrates the propagation of an intense pulsed laser beam the wavelength of which is in the visible or near infrared region of the spectrum, i.e. shorter than 1800 nm, from the distal end of a handpiece to a skin target according to a prior art method. Handpiece 1001 comprises clear transmitting element 1002, such as a lens or a window, which transmits monochromatic beam 1007 emitted from the laser unit and impinges skin target 1004. The beam penetrates skin target 1004 and selectively impinges a subcutaneous skin structure to be thermally injured, such as collagen bundle 1005, blood vessel 1009, or hair follicle 1006. In this method, external pressure or vacuum is not applied to the skin.

30 **[0101]** Fig. 2 illustrates a prior art non-coherent intense pulsed light system from which light is fired to a skin target for e.g. treatment of vascular lesions, hair removal, or photorejuvenation. Handpiece 1010 comprises light guide 1011 which is in contact with skin target 1004. Beam 1012, which is generated by lamp 1013 and reflected from reflector 1014, is non-coherent and further reflected by the light guide walls. In some handpieces, such as those produced by Deka (Italy), a clear transmitting element is utilized, rather than a light guide. Chilling gel is often applied to the skin when such

35 a light system is employed. In this method, external pressure or vacuum is not applied to the skin, and the handpiece is gently placed on the skin target, so as to avoid removal of the gel layer, the thickness of which is desired to remain at approximately 0.5 mm.

**[0102]** Fig. 3 illustrates a prior art laser system similar to those of US Patent Nos. 5,595,568 and 5,735,844, which employs an optical component 1022 at the distal end thereof in contact with skin target 1004. Pressure is applied to skin target 1004, in order to expel blood from those portions of blood vessels 1025, as schematically illustrated by the arrows, which are in the optical path of subcutaneously scattered light, thereby allowing more monochromatic light to impinge hair follicle 1006 or collagen bundle 1005. Concerning hair removal, melanin is generally utilized as an absorbing chromophore.

45 **[0103]** Fig. 4 illustrates a prior art device 1031, such as that produced by LPG (France), which is in pressing contact with skin 1033 in order to perform a deep massage of cellulite adipose layer 1037. Device 1031 is formed with a convex surface 1039 in a central region of its planar skin contacting surface 1043. Device 1031 stimulates the flow of lymphatic fluids in their natural flow direction 1038 in order to remove toxic materials from the adjoining tissue. The stimulation of lymphatic fluid flow is achieved by applying a vacuum to the interior of device 1031 so that air is sucked therefrom in the direction of arrow 1034 of the skin. The application of the vacuum draws skin toward convex surface 1039 and induces

50 the temporary formation of skin fold 1040, which is raised in respect to adjoining skin 1033. Due to the elasticity of skin, skin fold 1040 returns to its original configuration, similar to the adjoining skin, upon subsequent movement of device 1031, while another skin fold is formed. As device 1031 is moved by hand 1036 of a masseur in direction 1044 of the device, similar to natural flow direction 1038, the lymphatic fluids flow in their natural flow direction. However, the lymphatic fluids will not flow if device 1031 were moved in a direction opposite to direction 1044. Wheels 1035 enable constant

55 movement of device 1031.

**[0104]** In some cellulite massage devices, such as those produced by Deka (Italy) or the Lumicell Touch (USA), a low power continuous working infrared light source with a power level of 0.1- 2 W/cm<sup>2</sup> provides deep heating of the cellulite area and additional stimulation of lymphatic flow. Such a light source is incapable of varying the temperature by more

than 2-3 °C, since higher temperatures would be injurious to the tissue and cause hyperthermia. Consequently these massage devices are unable to attain the temperatures necessary for achieving selective thermal injury of blood vessels, hair follicles or for the smoothening of fine wrinkles. Due to the movement of the device, the amount of optical energy, e.g. by means of an optical meter, to be applied to the skin cannot be accurately determined.

5 **[0105]** Fig. 5 illustrates a prior art hair removal device, similar to the device of US Patent No. 5,735,844, which is provided with a slot 1052 within a central region of skin contacting surface 1051 of handpiece 1050. When handpiece 1050 is placed on skin surface 1058 and a vacuum is applied to the handpiece via opening 1053, skin fold 1054 is formed. A narrow slot 1052 induces formation of a correspondingly longer skin fold 1054. Optical radiation is transmitted to the two opposed sides 1056 of skin fold 1054 by a corresponding optical fiber 1055 and optical element 1057. Upon application of the vacuum, skin fold 1054 is squeezed to prevent blood flow therethrough. This device is therefore intended to reduce the concentration of blood within skin fold 1054, in order to increase illumination of melanin-rich hair shafts, in contrast with the apparatus of one embodiment of this invention by which blood concentration is increased within the slight vacuum-induced skin protrusion so as to induce increased light absorption, as will be described hereinafter. Furthermore, this prior art device, due to the reduced concentration of blood within skin fold 1054, is not suitable for treatment of vascular lesions, photorejuvenation, or the method of hair removal which is aided by the absorption of optical energy by blood vessels that surround or underly hair follicles (as opposed to the method of hair removal which is aided by the absorption of optical energy by melanin).

10 **[0106]** Although the application of a vacuum to a skin surface has been employed in the prior art to supplement skin treatments performed by means of optical energy, many significant differences between prior art apparatus for a vacuum-assisted light-based skin treatment to that of the present invention are evident:

a) The prior art application of vacuum is intended to remove smoke or vapors caused by the light-based ablation of a skin surface. By the apparatus of the present invention, in contrast, the optical energy does not interact with the skin surface, but rather is targeted to subcutaneous skin structures without producing smoke or vapors.

25 b) In order to remove smoke and vapors produced by a prior art light-based skin treatment, a flushing process is required whereby the produced smoke and vapors are purged and replaced by clean air. A low vacuum level is therefore generated, since if a high level vacuum were generated, the treatment handpiece would be prevented from being lifted and displaced from one skin target to another. In contrast, a high vacuum level of approximately 0 atmospheres is generated in the method of the present invention to sufficiently draw the skin into the vacuum chamber and to therefore facilitate the treatment of a skin disorder, yet the treatment handpiece may be quickly repositioned from one skin target to another.

30 c) Since smoke or vapor removal by means of prior art apparatus prevents the same from adhering to the distal window of a light source, the vacuum application by prior art apparatus should immediately follow each light treatment pulse. The apparatus of one embodiment of the present invention, in contrast, stimulates an increase in blood vessel concentration by applying the vacuum in order to increase light absorption, and therefore the vacuum needs to be applied prior to the firing of the treatment beam.

35 d) Prior art apparatus does not provide means to temporarily modulate the vacuum level. In contrast, the apparatus of the present invention has control means for modulating the applied vacuum level, by which the optical absorptivity of a skin target may be adjusted in order to effect a desired treatment.

40 e) Evacuation of skin ablation and of smoke or debris by means of prior art apparatus precludes employment of a protective gel layer over the skin, since the gel forms a barrier between the skin surface and the ambient air. Even if a prior art apparatus were conducive to the application of gel, no provision is made to prevent obstruction of the vacuum pump. In contrast, the apparatus of the present invention allows for the application of gel to the skin prior to a vacuum-assisted non-ablative treatment, since the light-based treatment is subcutaneous, and furthermore, provides means for preventing the obstruction of the vacuum pump.

45 f) With respect to apparatus of the prior art which is intended to induce blood expulsion from local skin tissue, the treatment beam is limited, to a laser beam of approximately 5 mm. If the treatment beam were significantly larger, e.g. 40 mm, blood expulsion would not be uniform and instantaneous, and therefore blood may remain in the skin tissue after a laser beam has been fired. In contrast, the apparatus of the present invention is suitable for performing skin treatments when the treatment beam is 40 mm, and furthermore is suitable for performing skin treatments by means of an IPL unit having a beam diameter which is significantly larger than that of a laser unit.

50 g) Prior art vacuum-assisted light-based skin treatment devices are known only to reduce the concentration of blood within a skin target, in order to increase the exposure of the skin target to the treatment light. The apparatus of the present invention, however, employs a vacuum chamber overlying the skin target, as will be described hereinafter, which does not necessarily expel blood from the epidermis of the skin target, but rather increases the blood volume fraction within the skin target.

55 **[0107]** Figs. 22 and 23 illustrate two vacuum chamber configurations, respectively, which induce different blood transfer

effects. In Fig. 22, vacuum chamber 100 is configured to induce the expulsion of blood 140 from skin target 130 to peripheral skin area 135, as indicated by the direction of the arrows, while vacuum chamber 200 of Fig. 23 is configured to induce blood transfer from peripheral skin area 210 to skin target 230, as indicated by the direction of the arrows.

**[0108]** The direction of blood transfer is dependent on the ratio of the skin target diameter to the thickness of the vacuum chamber walls. In Fig. 22, vacuum chamber 100 has thin walls 105 which serve to squeeze blood while peripheral skin area 135 slides under walls 105 as skin target 130 is drawn proximally. As walls 105 are thinner or sharper, the localized pressure under the walls is increased, resulting in a more effective squeezing of blood in the same direction as the skin sliding direction and outwardly from walls 105. On the other hand, as shown in Fig. 23, relatively thick support elements 250 of vacuum chamber 200 induce blood transfer towards skin target 230. Due to the increased thickness of support elements 250, the frictional force applied by support elements 250 onto the underlying skin surface is increased relative to that applied by walls 105 of Fig. 22, and therefore peripheral skin area 210 is prevented from sliding under support elements 250. As support elements 250 press on the underlying skin surface, albeit by a localized pressure less than applied by walls 105 of Fig. 22, the corresponding blood vessels are squeezed and blood is forced to flow towards skin target 230.

**[0109]** Fig. 6 illustrates the apparatus according to an embodiment of the invention, which is generally designated by numeral 1070. Apparatus 1070 comprises light source 1071, handpiece 1073 provided with clear transmitting element 1076 at its distal end, an evacuation unit which is designated by numeral 1090, and preferably a pressure indicator (not shown) for indicating the pressure within the vacuum chamber.

**[0110]** Evacuation unit 1090 comprises vacuum pump 1080, vacuum chamber C, and conduits 1078 and 1079 in communication with chamber C. Vacuum chamber C, which is placed on skin surface 1075, is formed with an aperture (not shown) on its distal end and is provided with a clear transmitting element 1076 on its proximate end. Vacuum chamber C is integrally formed with handpiece 1073, such that cylindrical wall 1091 is common to both handpiece 1074 and vacuum chamber C. Element 1076 is transparent to beam 1074 of intense pulsed monochromatic or non-coherent light which is directed to skin target T. Element 1076 is positioned such that beam 1074 is transmitted in a direction substantially normal to skin surface 1075 adjoining skin target T. The ratio of the maximum length to maximum width of the aperture, which may be square, rectangular, circular, or any other desired shape, ranges from approximately 1 to 4. Since the aperture is formed with such a ratio, skin target T is proximally drawn, e.g. 1 mm from skin surface 1075, and is slightly deformed, as indicated by numeral 1087, while increasing the concentration of blood in skin target T. Likewise, employment of an aperture with such a ratio precludes formation of a vacuum-induced skin fold, which has been achieved heretofore in the prior art and which would reduce the concentration of blood in skin target T.

**[0111]** Wall 1091 is formed with openings 1077 and 1084 in communication with conduits 1078 and 1079, respectively. The two conduits have a horizontal portion adjacent to the corresponding opening, a vertical portion, and a long discharge portion. Openings 1077 and 1084 are sealed with a corresponding sealing element 1093, to prevent seepage of fluid from the vacuum chamber. Conduit 1079 is also in communication with vacuum pump 1080, which draws fluid, e.g. air, thereto at subatmospheric pressures. U-shaped vacuum chamber C is therefore defined by clear transmitting element 1076 of the handpiece, slightly deformed skin surface 1087, wall 1091 and conduits 1078 and 1079.

**[0112]** A suitable light source is a pulsed dye laser unit, e.g. produced by Candela or Cynosure, for the treatment of vascular lesions, which emits light having a wavelength of approximately 585 nm, a pulse duration of approximately 0.5 microseconds and an energy density level of 10 J/cm<sup>2</sup>. Similarly any other suitable high intensity pulsed laser unit, such as a Nd:YAG, pulsed diode, Alexandrite, Ruby or frequency doubled laser, operating in the visible or near infrared region of the spectrum may be employed. Similarly, a laser unit generating trains of pulses, such as the Cynosure Alexandrite laser, the Lumenis "Quatim" IPL or Deka "Silkapiil". The emitted light is transmitted via optical fiber 1072 to handpiece 1073. Handpiece 1073 is positioned such that clear transmitting element 1076 faces skin surface 1087. Beam 1074 propagating towards slightly protruded skin surface 1087 is substantially normal to skin surface 1075.

**[0113]** Following operation of vacuum pump 1080, air begins to become evacuated from vacuum chamber C via conduit 1079. Occluding conduit 1078, such as by placing finger 1083 of an operator on its outer opening increases the level of the vacuum within chamber C to a pressure ranging from 200 to 1000 millibar. The application of such a vacuum slightly draws skin target T towards chamber C without being pressed, as has been practiced heretofore in the prior art, thereby increased the concentration of blood vessels within skin target T. The efficacy of a laser unit in terms of treatment of vascular lesions is generally greater than that of the prior art, due to the larger concentration of blood vessels in skin target T, resulting in greater absorption of the optical energy of beam 1074 within bodily tissue.

**[0114]** The operator may fire the laser following application of the vacuum and the subsequent change in color of skin target T to a reddish hue, which indicates that the skin is rich in blood vessels. The time delay between the application of the vacuum and the firing of the laser is based on clinical experience or on visual inspection of the tissue color.

**[0115]** Fig. 7 illustrates another embodiment of the present invention wherein the operation of the vacuum pump and of the pulsed laser or non-coherent light source is electronically controlled. The depth of light penetration within the tissue may be controlled by controlling the time delay between application of the vacuum and the firing of the pulsed light. If the time delay is relatively short, e.g. 10 msec, blood vessel enrichment will occur only close to the surface of

the skin at a depth of approximately 0.2 mm, while if the delay is approximately 300 msec, the blood vessel enrichment depth may be as great as 0.5-1.0 mm.

**[0116]** Apparatus 1170 comprises handpiece 1101, laser system 1116, evacuation unit 1190 and control unit 1119.

**[0117]** Laser system 1116 includes a power supply (not shown), a light generation unit (not shown), and power or energy detector 1130 for verifying that the predetermined energy density value is applied to the skin target. Handpiece 1101 held by the hand of the operator is provided with lens 1104, which directs monochromatic beam 1105 transmitted by optical fiber 1103 from laser system 1116 to skin target area 1140. Clear transmitting element 1100 defining vacuum chamber 1106 is generally in close proximity to skin surface 1142, at a typical separation H of 1-2 mm and ranging from 0.5 to 4 mm, depending on the diameter of the handpiece. The separation is sufficiently large to allow for the generation of a vacuum within chamber 1106, but less than approximately one-half the diameter of the window 1100, in order to limit the protrusion of skin target 1140 from the adjoining skin surface 1142. By limiting the separation of element 1100 from skin surface 1142 while maintaining the vacuum applied to skin target 1140, formation of a skin fold is precluded while more blood may be accumulated in a smaller skin thickness. Therefore a significant local rise in the temperature of a blood vessel, which ranges from 50-70°C, is made possible.

**[0118]** Evacuation unit 1190 comprises vacuum chamber 1106 which is not U-shaped, miniature vacuum pump 1109 suitable for producing a vacuum ranging from 200-1000 millibar, conduit 1107 and control valve 1111 through which subatmospheric fluid is discharged from chamber 1106, and miniature pressurized tank 1110 containing, e.g 100 ml, which delivers air through conduit 1112 and control valve 1108 to chamber 1106. If so desired, a clear transmitting element need not be used, and vacuum chamber 1106 defined by lens 1104 will have an accordingly larger volume.

**[0119]** Control unit 1119 comprises the following essential elements:

a) Display 1115 of the energy density level of the monochromatic light emitted by laser system 1116 and a selector for selecting a predetermined energy density.

b) Confirmation indicator 1120 which verifies that the selected energy density is being applied to the skin. Control circuitry deactivates the laser power supply if a beam having an energy density significantly larger than the predetermined value is being fired.

c) Display 1122 concerning the pulse structure, such as wavelength, pulse duration and number of pulses in a train.

d) Control circuitry 1123 for selecting the time delay between operation of vacuum pump 1109 and laser system 1116.

e) Selector 1124 for controlling the vacuum level in vacuum chamber 1106 by means of pump 1109.

f) Control circuitry 1126 for controlling the vacuum duty cycle by regulating the operating cycle of vacuum pump 1109, the open and close time of control valve 1111, the average vacuum pressure, the vacuum modulation frequency, and the repetition rate.

g) Control circuitry 1143 for delivering fluid from positive pressure tank 1110 by controlling the duty cycle of control valve 1108.

h) Light detector 1185 for sensing whether light is impinging onto skin target 1140.

**[0120]** Tank 1110, in which air having a pressure ranging from 1-2 atmospheres is contained, provides a fast delivery of less than 1 msec of air into chamber 1106, as well as a correspondingly fast regulation of the vacuum level therein by first opening control valves 1108 and 1111 and activating vacuum pump 1109. After a sufficient volume of fluid, e.g 1 ml, is delivered to chamber 1106, control valve 1108 is closed. Control circuitry 1126 and 1143 then regulate the operation of the control valves so to maintain a predetermined level of vacuum. Upon achieving the predetermined vacuum level, control circuitry 1123 fires laser system 1116 after the predetermined time delay, which may range from 1-1000 msec.

**[0121]** Control unit 1119 may also be adapted to increase the pressure in vacuum chamber 1106 to atmospheric pressure (hereinafter in "a vacuum release mode") following deactivation of the pulsed light beam source, to allow for effortless repositioning of the vacuum chamber to another skin target. In order to achieve a fast response time between the deactivation of the light source and the pressure increase within the vacuum chamber prior to repositioning the vacuum chamber to another skin target, light detector 1185 is employed to detect the light emitted by the treatment light source. When the light detector ceases to detect light emitted by the light source, a suitable command is transmitted to control unit 1119, whereupon the latter generates a command to open control valve 1111, in order to increase the vacuum chamber pressure. Alternatively, the vacuum within the vacuum chamber may be released by depressing a pneumatically or electrically actuated button located on the handpiece, following deactivation of the light source. Employment of a light detector which triggers the release of the vacuum in the vacuum chamber in order to allow for the speedy repositioning of the treatment handpiece has particular significance in conjunction with fast treatment systems such as the hair removal "Light Sheer" diode system produced by Lumenis, which operates at a fast rate of 1 pulse per second.

**[0122]** Fig. 8 illustrates apparatus 1270, which comprises a non-coherent intense pulsed light system similar to that described with respect to Fig. 2 and provided with Xe flashlamp 1201, such as one manufactured by Lumenis, Deka, Palomar, or Syneron. Reflector 1202 reflects the emitted light 1207 to light guide 1208. Distal end 1203 of light guide



1208 is separated 1-2 mm from skin surface 1242 to allow for the generation of a vacuum in vacuum chamber 1206 without compromising treatment efficacy by limiting the protrusion of the skin target from the adjoining skin surface 1242.

**[0123]** Figs. 15a-b illustrate another embodiment of the invention wherein apparatus 1670 comprises a vacuum chamber 1601 which is attached to intense pulsed light guide 1602. Fig. 15a schematically illustrates vacuum chamber 1601 prior to attachment to the light guide, and Fig. 15b schematically illustrates the attachment of vacuum chamber 1601 to light guide 1602. Vacuum chamber 1601 has walls 1608, side openings 1605 formed in walls 1608, and proximate cover 1612 formed with a proximate aperture 1607 having dimensions substantially equal to the cross section of light guide 1602. Attachment means 1604 facilitates the attachment of vacuum chamber 1601 to light guide 1602 or to any element adapted to protect the light guide. Attachment means 1604 preferably also seals the interface between cover 1612 and light guide 1602, to prevent the infiltration of air into vacuum chamber 1601 after the generation of a vacuum therein. Clear transmitting element 1625 of light guide 1602 also serves to prevent an increase in vacuum chamber pressure. Once vacuum chamber 1601 is attached to light guide 1602, the vacuum chamber may be placed on a selected skin surface 1603. After a vacuum is generated within chamber 1601, skin target 1606 is drawn into the interior of vacuum chamber 1601, whereupon pulsed light beam 1620 may be fired towards skin target 1606. Vacuum chamber 1601 may be advantageously attached to the distal end of any existing IPL or laser source, to convert the light source into an apparatus for enhancing the absorption of light in targeted skin structures, in accordance with the present invention. This embodiment is particularly useful when the distal end of the light source is provided with an integral skin chilling device.

**[0124]** Fig. 9 illustrates the placement of apparatus 1370 onto arm 1310. Apparatus 1370 comprises handpiece 1301, evacuation unit 1390, and skin chiller 1300 for cooling the epidermis of arm 1310, which is heated as a result of the impingement of monochromatic light thereon. Skin chiller 1300 is preferably a metallic plate made of aluminum, which is in contact with the epidermis and cooled by a thermoelectric cooler. The temperature of the plate is maintained at a controlled temperature, e.g. 0°C. The chilled plate is placed on a skin region adjacent to skin target 1340. The epidermis may be chilled prior to the light treatment by other suitable means, such as by the application of a gel or a low temperature liquid or gas sprayed onto the skin target.

**[0125]** It will be appreciated that the utilization of a U-shaped vacuum chamber 1306 for the evacuation of vapors which condense on clear transmitting element 1376 is particularly advantageous when a skin chiller in permanent contact with the handpiece outer wall is employed. Such a skin chiller results in condensation of vapors on the transmitting element that would not be evacuated without employment of an evacuation unit in accordance with the present invention. Alternatively, the skin chiller may be releasably attached to the vacuum chamber.

**[0126]** Fig. 10 schematically illustrates the effect of applying a subatmospheric pressure to a skin target, in accordance with the present invention, in order to enhance the absorption of light by blood vessels within the skin target. For clarity, the drawing illustrates the effect with respect to a single blood vessel; however, it should be appreciated that many blood vessels contribute to the effect of increased blood transport whereby a plurality of blood vessels are drawn to the epidermis, resulting in increased absorption of the optical energy. The protrusion of the skin target relative to the adjoining skin surface is also shown in disproportionate fashion for illustrative purposes.

**[0127]** The increase in light absorption within blood vessels due to the application of a vacuum in the vicinity of a skin target depends on the vacuum level, or the rate of vacuum modulation, and the skin elasticity which is reduced with increased age. As shown, blood vessel 1329 of diameter D is in an underlying position relative to vacuum chamber 1326. By applying a vacuum by means of evacuation unit 1390, blood flow is established in blood vessel 1329 in the direction of arrow M, due to a difference of pressures between points A and B closer and farther from vacuum chamber 1326, respectively. If the blood vessel is a vein, the flow will be established in only one direction, due to the influence of the corresponding vein valve.

**[0128]** According to the Hagen-Poiseuille equation concerning the flow of viscous fluids in tubes, the discharge from a tube and consequently the duration of flow therethrough depends on a pressure gradient along the tube, the fourth power of the diameter of the tube, and the length thereof. For example, diameters of 100 microns are common for capillaries adjacent to the papillary dermis at a depth of approximately 200 microns and 500-micron blood vessel diameters can be found in the hair bulb at a depth of 3 mm. A typical blood vessel length is approximately 1-2 cm. It will be appreciated that although the blood vessel diameters generally increase with depth, the pressure gradient along the blood vessel is smaller at deeper layers of the skin. As a result, for a given pressure, such as the application of a zero millibar vacuum, each depth from the skin surface corresponds to a characteristic time response for being filled by blood. As a result, modulation of the vacuum by opening and closing control valve 1111 (Fig. 7) controls the flow of blood through blood vessels and consequently controls the degree of light absorption by a blood vessel at a given depth from skin surface 1342. In a realistic situation wherein a plurality of blood vessels are located within a skin target, each skin layer is characterized by a different modulation frequency which typically ranges between 100 Hz for upper layers and 1 Hz for the deep layers under the hair follicles. By opening control valves 1108 and 1111 (Fig. 7) by a varying frequency, the operator may modulate the vacuum applied to the skin target and thereby vary the blood richness of different skin layers.

**[0129]** The operator typically determines an instantaneous modulation frequency of control valves 1108 and 1111 by

visually inspecting the skin target and viewing the degree of redness thereat in response to a previous control valve modulation frequency. In addition to improving the treatment efficacy, an increased degree of redness within the skin target advantageously requires a lower energy density of intense pulsed light for achieving blood coagulation or blood heating resulting in the heating of the surrounding collagen. Alternatively, an erythema, i.e. skin redness, meter, e.g. produced by Courage-Hazaka, Germany, may be employed for determining the degree of redness, in order to establish the necessary energy density for the treatment.

**[0130]** For example, a modulation frequency as high as 40 Hz or the firing of a Dye laser unit approximately 1/40 seconds after application of a vacuum may be necessary for applications of port wine stains. In contrast, a delay of approximately a half second for fine wrinkle removal and of approximately 1 second for hair removal may be needed for a depth of 1-3 mm under the skin surface.

**[0131]** Fig. 11 illustrates the concentration of a plurality of blood vessels 1329 in a skin target 1340, which results in the increase of redness of skin and enhanced absorption of light with respect to the hemoglobin absorption spectrum and scattering properties of skin. Light absorption is enhanced by a larger number of blood vessels per unit volume due to the correspondingly larger number of light absorbing chromophores. The beneficial effect of vacuum assisted absorption by Dye lasers or any yellow light, which is strongly absorbed by hemoglobin, is more pronounced on white or yellow skin not rich in blood vessels, such as that of smokers. Such types of skin suffer from enhanced aging and require photorejuvenation, the efficacy of which is improved with the use of the present invention. Enhanced absorption of light is also advantageously achieved when infrared lasers and intense pulsed light sources are employed.

**[0132]** Fig. 12 is a photograph illustrating the treatment of a fine wrinkle 1401 by means of a vacuum assisted handpiece according to the current invention, which was taken one-half of a second after the application of a vacuum. Circles 1402-4 indicate the sequential treatment spots. The color in the circle 1403 has changed.

**[0133]** Fig. 23 illustrates another embodiment of the invention, by which blood vessel concentration within a skin target is increased by selecting the thickness of the supporting elements of the vacuum chamber. Vacuum chamber 200 placed on skin target 230 comprises cover 205, clear transmitting element 215 centrally retained within cover 205, relatively thin annular leg 240 having a thickness of  $T_2$  positioned below cover 205 at the outer periphery thereof, relatively thick annular support element 250 of thickness  $T_1$  separated from leg 240 and positioned below cover 205 at skin area 210 adjoining skin target 230, and conduits 255 formed within cover 205 by which the vacuum is applied to the vacuum chamber. Each conduit 255 is provided with an inner inlet 282 and an outer inlet 284. Each inner inlet 282 communicates with volume  $V_1$  interior to annular support element 250 and each outer inlet 284 communicates with volume  $V_2$ , which has a significantly smaller volume than volume  $V_1$  and is formed between support element 250 and surrounding annular leg 240.

**[0134]** When a vacuum is applied to vacuum chamber 200, the pressure differential between the surrounding ambient air pressure and the generated vacuum within the vacuum chamber urges vacuum chamber 200 to be in pressing relation with the skin adjoining skin target 230. The resultant force associated with the pressure differential acts on both legs 240 and on support elements 250. Since a vacuum is applied onto the two sides of support element 250 via volumes  $V_1$  and  $V_2$ , the resultant force transmitted to underlying skin area 210 by support element 250 produces a substantially uniform squeezing pressure. By virtue of thin vacuum volume  $V_2$ , legs 240 serve as a means to stabilize vacuum chamber 200, which is particularly useful on a skin area that is not completely planar, such as in the vicinity of a bone.

**[0135]** The wide area pressure applied by support element 250 onto skin area 210 directs the expelled blood towards skin target 230 as well as towards leg 240. Air evacuated from volume  $V_1$  through inner inlets 282 causes skin target 230 to be proximally drawn and blood to be transported from peripheral skin area 210 towards skin target 230. Support element 250 therefore induces inward blood transport from peripheral skin areas 210 to skin target 230, as represented by arrow 272, resulting in a significant increase in the blood volume fraction within skin target 230. After the blood concentration within skin target 230 has sufficiently increased, light beam 260 is suitable for treating vascular lesions with a wavelength well absorbed by the blood vessels within the skin target, and therefore an energy density less than that of the prior art is fired. The depth of light absorption within skin target 230 can be controlled by changing the thickness  $T$  of support elements 250.

**[0136]** Air evacuated from volume  $V_2$  through a corresponding outer inlet 284 causes skin area 290 underlying corresponding volume  $V_2$  to be drawn proximally. Skin area 290 is then pressed by the edge of support element 250 so that blood, as represented by arrow 292, is outwardly transported from support element 250 to leg 240. By inducing outward transport of blood, the blood volume fraction and therefore the depth of light absorption within skin target 230 may be further controlled.

**[0137]** It will be appreciated that the blood concentration within skin target 230 can be increased solely by the pressure applied by support element 250, without use of legs 240. Likewise, support elements 1325, 1345, and 1502 illustrated in Figs. 10, 11, and 13, respectively, induce blood transport towards the skin target without need of additional legs.

**[0138]** Fig. 13 illustrates apparatus 1570 which increases blood vessel concentration within a skin target without use of a handpiece. Apparatus 1570 comprises evacuation unit 1590 having a transparent vacuum chamber 1501 and a clear transmitting element 1506, which is made of a thin, transparent polymer such as polycarbonate or of glass, which

is transparent to visible or near infrared light. Vacuum chamber 1501 has a diameter of 5-20 mm and a height of approximately 1-3 mm, in order to avoid excessive protrusion of the skin. Chamber 1501 is preferably cylindrical, although other configurations are also suitable. A soft silicon rim (not shown) is adhesively affixed to the periphery of the chamber 1501, in order to provide good contact with skin surface 1542. Conduit 1503 in communication with control valve 1504 allows for the evacuation of vacuum chamber 1501 by means of a miniature vacuum pump (not shown) and control unit 1505. After chamber 1501 is placed on skin target 1540, pulsed beam 1508 from any existing intense pulsed laser or light source 1509 which operate in the visible or near infrared regions of the spectrum may propagate therethrough and effect treatment of a skin disorder. Vacuum chamber 1501 and conduit 1503 are preferably disposable. When vacuum chamber 1501 is disposable, clear transmitting element 1506 is insertable within a suitable groove formed within the housing of vacuum chamber 1501. Vacuum chamber 1501 may be hand held or may be releasably attachable to the handpiece of light source 1509. When hand held, vacuum chamber 1501, control unit 1505, and a display (not shown) may be integrated into a single device. The treatment may therefore be performed with the use of two hands, one hand, e.g. hand 1530, holding the integrated vacuum chamber device by means of handle 1531 and the other holding the treatment light source. The advantage of this apparatus is its low price and its ability to interact with any intense pulsed laser or non-coherent light source which is already installed in a health clinic.

**[0139]** The absorption of visible intense pulsed light in blood vessels when vacuum is applied to a skin target may be enhanced by the directing electromagnetic waves to the skin target. Radio frequency waves operating in the range of 0.2-10 Mhz are commonly used to coagulate tiny blood vessels. The alternating electrical field generated by a bipolar RF generator, such as produced by Elman, USA or Synron, Canada, follows the path of least electrical resistance, which corresponds to the direction of blood flow within blood vessels. A monopolar RF may also be employed, such as manufactured by Thermage, USA.

**[0140]** Fig. 14 illustrates apparatus 1870 which comprises intense pulsed laser or intense pulsed light source 1821, RF source 1811, and evacuation unit 1890. Evacuation unit 1890 comprises vacuum chamber 1801, which is placed on skin surface 1802 to be treated for vascular lesions, miniature vacuum pump 1805, and control valve 1804 for regulating the level of the vacuum in chamber 1801. Clear transmitting element 1806 is positioned in such a way that beam 1820 generated by light source 1821 propagates therethrough and impinges skin surface 1802 at an angle which is substantially normal to the skin surface.

**[0141]** RF source 1811 is a bipolar RF generator which generates alternating voltage 1807 applied to skin surface 1802 via wires 1808 and electrodes 1809. Alternatively, the RF source is a monopolar RF generator with a separate ground electrode. Electric field 1810 generally follows the shape of blood vessels 1813, which are the best electrical conductors in the skin. Due to the concentration of blood vessels 1813 in the epidermis, the depth of which below skin surface 1802 depending on the vacuum level and the frequency of vacuum modulation, the combined effect of optical energy in terms of beam 1820 and pulsed RF field 1810 heats or coagulates the blood vessels. Control valve 1804 is regulated by means of control unit 1812. A first command pulse 1 of control unit 1812 controls valve 1804 and a second command pulse 2 controls a delayed radio frequency pulse as well as a delayed light source pulse.

**[0142]** When a vacuum chamber is placed on a skin target, the apparatus provides an additional advantage in terms of the capability of alleviating pain that is normally caused during e.g. the treatment of hair with intense pulsed monochromatic or non-coherent light.

**[0143]** As shown in Fig. 16, apparatus 1970 is configured so as to bring skin target 1960, when a vacuum is applied, in contact with clear transmitting element 1906, e.g. made from sapphire, which is secured to the proximate end of vacuum chamber 1901. The Applicant has surprisingly discovered that the immediate sharp pain which is normally sensed during a light-based skin treatment is alleviated or eliminated when a skin target contacts the clear transmitting element. The level of the applied vacuum is suitable for drawing skin target 1960 towards vacuum chamber 1901 by a slight protrusion of K, e.g. 2-4 mm, with respect to adjoining skin surface 1965, a distance which is slightly greater than the gap between clear transmitting element 1906 and the distal end of outer wall 1924 of vacuum chamber 1901. During generation of pulsed beam 1908 from any suitable intense pulsed laser or light source propagating through clear transmitting element 1906, whereby hair follicles 1962 located under the epidermis of skin target 1960 are treated by the generated optical energy, skin target 1960 is drawn to be in contact with clear transmitting element 1906. As skin target 1960 is drawn by the vacuum into vacuum chamber 1901 and contacts clear transmitting element 1906 by means of the resulting proximally directed force, the pain signals generated by the nervous system during the heating of hair follicles 1962, or of any other suitable targeted skin structure, of the patient are inhibited. Accordingly, the synchronization of an optimal delay between the application of the vacuum and firing of the light treatment pulse is a key factor in pain reduction, in order to ensure that skin target 1960 is in contact with clear transmitting element 1906 for a sufficiently long nerve inhibiting duration when pulsed beam 1908 is fired. Pain reduction is noticeable with use of this apparatus even when the energy level of the light directed to skin target 1960 is increased, an effect which normally causes an increase in immediate sharp pain.

**[0144]** Vacuum chamber 100 illustrated in Fig. 22 is also configured to alleviate the pain resulting from the firing of light beam 160 onto skin target 130. When a vacuum is applied onto vacuum chamber 100 via conduits 155, skin target

130 is drawn and contacts clear transmitting element 115. Instead of sensing immediate sharp pain during impingement of each treatment pulse with a skin area 136 of skin target 130, the magnitude of proximally directed force F resulting from the applied vacuum causes nerve 138 surrounding a corresponding hair bulb and extending to skin area 136 to be pressed onto clear transmitting element 115 for a sufficient duration to inhibit the pain sensation. Light beam 160 is of a wavelength which is well absorbed by hair follicles 139. By optimizing the time delay between application of the vacuum and the firing of light beam 160, the pain sensation is sufficiently inhibited and the energy density of light beam 160 need not be decreased.

**[0145]** The apparatus for alleviating pain during vacuum-assisted light-based treatments of the skin may include a control device (not shown) for adjusting the vacuum level generated by the vacuum pump, as well as the time delay between the application of the vacuum and the firing of light beam. The control device preferably has a plurality of finger depressable buttons, each of which is adapted to set the vacuum pump and light source at a unique combination of operating conditions so as to generate a predetermined vacuum level within vacuum chamber 100 and to result in a predetermined time delay between the operation of the vacuum pump and the firing of light beam 160, and a display to indicate which button was depressed. The apparatus may also comprise control valves in electrical communication with the control device for evacuating air into vacuum chamber during a vacuum applying mode and for introducing air therein during a vacuum release mode, respectively. The health professional is aware of the anticipated pain level that a patient generally senses when one of these buttons is depressed. If the pain threshold of a patient is relatively low or if the application of the vacuum by the vacuum chamber onto the skin target is annoying, the health professional may change the combination of operating conditions by depressing a different button. Alternatively, the pain threshold of a patient may be objectively determined by an electrical measurement of a muscle reflex in response to pain.

**[0146]** As skin target 130 is pressed onto clear transmitting element 115 during the application of the vacuum, blood is displaced from skin target 130 to peripheral skin area 135. Although the blood fraction volume in peripheral skin area 135 is increased, the latter is nevertheless liable to be damaged by the treatment light, which may diffuse subcutaneously from skin target 130 to skin area 135. To counteract the potential thermal injury to skin area 135, heat absorbing gel (not shown in the figure) is applied to skin target 130 prior to application of the vacuum and is subsequently squeezed to peripheral skin area 135 by means of transmitting element 115. The displaced gel therefore advantageously protects peripheral skin area 135 from being injured by subcutaneously diffused treatment light.

**[0147]** The apparatus may be advantageously provided with means to prevent the obstruction of the vacuum chamber conduits by heat releasing gel applied to the skin target prior to the treatment. As shown in Figs. 24A and 24B, gel 185 is squeezed to the periphery of vacuum chamber 180 after application of a vacuum. When vacuum chamber 180 is displaced from skin area 190 to skin area 192, further gel is squeezed and accumulates, as shown in Fig. 24B. The gel is eventually aspirated into the vacuum chamber conduits, causing a significant risk of obstruction thereto when a large-diameter treatment beam normally associated with an IPL unit is used and necessitating the employment of a correspondingly large-diameter vacuum chamber. Without employing means to prevent passage of the gel, a large quantity of gel is liable to be drawn through the conduits and to the vacuum pump, eventually resulting in the malfunction of the latter and in less efficacious treatments. Also, aspirated gel tends to contaminate the vacuum chamber, and the cleaning or sterilization of the vacuum chamber prior to the treatment of another patient is difficult.

**[0148]** Referring back to Fig. 16, vacuum chamber 1901 has two passageways 1930 through which air is evacuated therefrom. Each passageway 1930, which is in fluid communication with the interior of vacuum chamber 1901, is defined by outer wall 1924, vertical portion 1926, and cylindrical horizontal wall 1930 connected to both outer wall 1924 and vertical portion 1926. The distal end of vertical portion 1926 is connected to clear transmitting element 1906, vertically spaced above, and interiorly spaced from, the distal end of outer wall 1924 placed on skin surface 1965, and is connected to vertical portion 1926 of passageway 1930. The top of horizontal passageway wall 1930 is vertically spaced above outer wall 1924, and vacuum chamber 1901 is therefore considered to be U-shaped. Each horizontal wall 1930 terminates with an opening 1917, which is separated from the distal end of outer wall 1924 by P and is laterally separated from centerline 1969 of vacuum chamber 1901 by J. While the gel may be drawn by the applied vacuum or may laterally slide from skin target 1960 after being pressed by clear transmitting element 1906, dimensions P and J are selected so as to ensure that the volume of the passageways 1930 and of the chamber interior between wall 1924 and the adjacent surface of drawn skin target 1960 is sufficiently large to prevent the obstruction of corresponding opening 1917 by gel 1963. For example, a vacuum chamber having a height K of 2 mm, a wall opening diameter of 3 mm, a separation P of 10 mm from the opening to the distal end of the wall, and a lateral separation J of 20 mm from the vacuum chamber centerline to the opening is sufficient to prevent obstruction of the opening by gel.

**[0149]** Fig. 17 illustrates another arrangement for preventing vacuum pump suction of gel. The arrangement includes trap 1920, conduit 1940 through which gel and air are drawn from the vacuum chamber to trap 1920, and conduit 1945 through which air is drawn from trap 1920 to the vacuum pump, all of which may be disposable. Air evacuated from the vacuum chamber through opening 1917 flow through conduits 1940 and 1945 until introduced to the inlet port of the vacuum pump. The gel which is evacuated from the vacuum chamber collects within trap 1920. Trap 1920 is periodically emptied so that the accumulated gel does not rise above the inlet of conduit 1945. Trap 1920 and conduits 1940 and

1945 are preferably made from a plastic hydrophilic material, to urge the gel to cling to the walls thereof rather than to be drawn through the conduits to the vacuum pump. As shown, gel 1966 clings to the walls of conduit 1940 and gel 1967 is collected on the bottom of trap 1920. The conduits may be suitably sized to prevent the passage of gel to the vacuum pump. For example, the diameter of conduit 1940 at the vacuum wall opening is 30 mm and narrows to a diameter of 10 mm at the discharge to trap 1920, and the diameter of conduit 1945 at the inlet side is 5 mm and is 10 mm at the discharge side in the vicinity of the the vacuum pump inlet port.

**[0150]** Other arrangements for preventing vacuum pump suction of gel may also be employed. For example, the gel may be bound to a suitable ion exchange resin introduced into trap 1920 and thereby be prevented from being drawn through conduit 1945. If so desired, a filter may be provided at the inlet of conduits 1940 and 1945.

**[0151]** Alternatively, gel may be prevented from exiting the vacuum chamber by increasing the diameter of conduit 1940 at the vacuum wall opening. Consequently, the inwardly directed force acting on the gel which has laterally slid from a drawn skin target by means of the atmospheric air introduced to the vacuum chamber via conduit 1940 during a vacuum release mode is sufficient to prevent the gel from exiting the vacuum chamber. A hydrophobic coating, such as silicon or teflon, may be applied onto the vacuum chamber walls, so that the gel will be prevented from adhering to the vacuum chamber walls, particularly during a vacuum release mode. Instead of adhering to the vacuum chamber walls, the gel falls to the skin surface. Advantageously, gel is therefore not transported to another skin target during the repositioning of the handpiece, but rather assumes the shape of the distal end of the vacuum chamber walls. If the distal end of the vacuum chamber walls is circular, for example, the gel that falls to the skin surface during a vacuum release mode is also circular, indicating to the health professional that is supervising the treatment that the given skin surface has already been impinged by the treatment light.

**[0152]** In Fig. 18, apparatus 1980 comprises a vacuum chamber having a detachable upper portion, so that the gel retained by the vacuum chamber interior walls may be removed therefrom, such as by dissolving the gel with salt or with any other suitable dissolving agent. Apparatus 1980 comprises upper portion 1983 having an open central area, clear transmitting element 1984 attached to upper portion 1983, vacuum chamber walls 1981, vacuum chamber cover 1982 perpendicular to walls 1981 and suitably sized so as to support upper portion 1983, and a plurality of attachment clips 1987 pivotally connected to a corresponding vacuum chamber wall 1981 for detachably securing upper portion 1983 to vacuum chamber cover 1982. Thin compliant sealing element 1988 is preferably attached to the periphery of vacuum chamber cover 1982, to prevent infiltration of atmospheric air into the vacuum chamber. Conduit 1940 is shown to be in communication with the interior of the vacuum chamber.

**[0153]** Fig. 25 illustrates another embodiment of apparatus for preventing the obstruction of vacuum chamber conduits by heat releasing gel during vacuum-assisted light-based treatments of the skin. Apparatus 400 comprises vacuum chamber 420, peristaltic pump 430, vacuum controller 440, control valve 450, and micro-switch 460.

**[0154]** The vacuum applying mode is initiated upon transmission of signal 445 to controller 440, following which peristaltic pump 430 is activated. Peristaltic pump 430 comprises hose 442 connected to conduit 425 in communication with the interior of vacuum chamber 420 and rotatable hub 446, from which a plurality of shoes and/or rollers 448 (referred to hereinafter as "pressing elements") radially extend. As hub 446 rotates, the pressing elements sequentially squeeze a different region of hose 442 and a volume of fluid entrapped by two adjacent pressing elements is thereby forced to flow unidirectionally through hose 442 by a positive displacement action towards end 449 thereof. Consequently, when peristaltic pump 430 is activated, air is drawn from the interior of vacuum chamber 420 to generate a vacuum therein ranging from 0-1 atmospheres. If a considerable amount of gel 405 accumulates within the periphery of vacuum chamber 420, the gel is also forced to flow within hose 442 without causing any obstruction to the latter. The gel that is discharged from end 449 of hose 442 falls onto skin surface 410, indicating that an adjoining skin target 415 has undergone a light-based treatment.

**[0155]** Micro-switch 460, or any other suitable skin contact detector, is adapted to sense the placement of the handpiece or of vacuum chamber 420, onto skin target 415. Micro-switch 460 generates signal 445 upon sensing the placement of vacuum chamber 420 on skin target 415. Control valve 450 is triggered by a light detector (not shown), which generates signal 455 upon detecting the termination of the light-based treatment pulse 470. Control valve 450 is opened after the generation of signal 455, to introduce atmospheric pressure air 452 to the interior of vacuum chamber 420 via passageway 456 and to thereby initiate the vacuum release mode. Signal 455 is also transmitted to controller 440, to deactivate peristaltic pump 430. The described automatic operation of peristaltic pump 430 therefore prevents the patient from suffering pain during the associated treatment. If so desired, the operation of peristaltic pump 430 may be manually overridden.

**[0156]** It will be appreciated that a peristaltic pump or a contact detector may be employed in conjunction with any other embodiment of the invention.

**[0157]** In another embodiment, the vacuum pump is an air pump. When air is evacuated from the vacuum chamber, a piston (not shown) which is normally closed by a spring is opened to allow air to be aspirated. During the vacuum release mode, the piston is set to its original position, returning air to the vacuum chamber and any aspirated gel to the skin surface.

**[0158]** Figs. 27A-C illustrate another embodiment of the invention wherein a vacuum pump is not needed for vacuum-assisted light-based treatments of the skin. Apparatus 600 comprises a vertically displaceable cover 610 to which clear transmitting element 615 is secured, chamber walls 620 in which vertically displaceable cover 610 is mounted, and sealing element 625 which is secured to the outer periphery of cover 610. Chamber walls 620 surround, and are of a similar shape as, cover 610.

**[0159]** When cover 610 is in its lowermost position, as shown in Fig. 27A, the cover is flush with skin surface 630 on which is applied a layer of gel 635. In this position, air is prevented from infiltrating between cover 610 and skin target 630, e.g. by means of a sealing element externally affixed to walls 620. When a proximally directed force represented by arrows 652 is applied to cover 610, as shown in Fig. 27B, the cover is raised while sealing element 625 resiliently contacts walls 620. Apparatus 600 is configured such that distal displacement of cover 610 is prevented after having been raised, without application of a subsequent distally directed force. While cover 610 is raised, a vacuum chamber 640 is produced internally to chamber walls 620, due to the increased volume between cover 610 and skin surface 630 while air is prevented from infiltrating therein. The vacuum generated within vacuum chamber 640 as a result of the proximal displacement of cover 610 ranges from 0-1 atmospheres and is suitable for drawing skin target 650 towards the displaced cover 610 as shown, in order to be subsequently impinged by a treatment pulse. When a distally directed force represented by arrows 654 is applied to cover 610 following the light-based treatment, as shown in Fig. 27C, cover 610 returns to its lowermost position in preparation for displacement to the next skin target. Aeration tube 675 in communication with a manually operated or control valve (not shown) may be employed to quicken distal displacement of cover 610 during a vacuum release mode by introducing atmospheric air to vacuum chamber 640 upon conclusion of the skin target treatment.

**[0160]** Proximally directed force 652 or distally directed force 654 may be generated manually by means of handles (not shown) attached to cover 610, or electrically by means of a plurality of solenoids 670 and/or by means of a spring assembly 660 deployed around the periphery of cover 610, as well known to those skilled in the art to achieve balanced displacement of the cover. Solenoids 670 are mounted such that one side of a solenoid is mechanically connected to displaceable cover 610 and the other side thereof is connected to a chamber wall 620. When electrical actuation of cover 610 is employed, command 608 generated by skin contact sensor 460 (Fig. 25) is transmitted to spring assembly 660 or solenoids 670 after a predetermined time delay following contact between cover 610 and skin surface 630, causing cover 610 to be proximally displaced upward with a proximally directed lifting force 652 comparable to that of a piston. By properly controlling solenoids 670, height H of the drawn skin target 650 relative to the adjoining skin surface 630 can be adjusted. Height H of the drawn skin is generally increased as the treatment spot is increased. For example, height H may be 2 mm for a treatment spot of 40 mm, while height H may be 0.5 mm for a treatment spot of 3 mm. Alternatively, height H may be adjusted to ensure that skin target 650 contacts clear transmitting element 615 for pain alleviation.

**[0161]** At times, a sufficiently high vacuum level for effecting a light-based treatment may not be produced within vacuum chamber 640, due to a malfunction. If a health professional notices that the distance between skin target 650 and clear transmitting element 615 is greater than a predetermined distance for effective treatment with an IPL or laser, the automatic control of cover 610 may be overridden. By reversing the direction of current within solenoids 670, one-time distally directed force 678 may be generated which urges cover 610 towards skin surface 630.

**[0162]** When the distal end of the treatment light source is positioned on chamber walls 620, cover 610 has a relatively low weight of approximately 50 gm. However, if the treatment handpiece is positioned on cover 610 such that the combined weight of the cover and handpiece is approximately 1 kg, the capacity of solenoids 670 needs to be increased, in order to raise both the cover and handpiece and to produce a vacuum within chamber 640.

**[0163]** Apparatus 600 advantageously provides low power consumption and increased compactness. When the handpiece is positioned on chamber walls 620, solenoids 670 are energized by a battery without need of draining wall current and only when cover 610 is needed to be vertically displaced. The energy requirement for raising cover 610 to a height of 2 mm is approximately 0.5 J for a typical 500-pulse large area treatment on the back or legs. Therefore an inexpensive 1.5 V battery is suitable for more than 1000 treatments.

**[0164]** Apparatus 600 also advantageously prevents accumulation of gel. When skin target 650 is drawn during a vacuum applying mode as shown in Fig. 27B, gel 635 is displaced to a peripheral skin area within vacuum chamber 640. However, when cover 610 returns to its original lowermost position as shown in Fig. 27C, skin target 650 is retracted. Gel 635 is then substantially uniformly spread underneath cover 610, due to the pressure applied by cover 610. Similarly when apparatus 600 is repositioned to another skin target, gel 635 does not accumulate.

**[0165]** The proximally directed force may be supplemented by means of a vacuum pump, which may be needed if an excessive amount of gel is applied to skin surface 630 or if it desired to indicate that skin target 650 has undergone a light-based treatment as described hereinabove.

**[0166]** Fig. 28 illustrates another embodiment of the invention which is suitable for pain alleviation. Apparatus 700 comprises vacuum chamber 705 and IPL treatment light source 710, e.g. one produced by Syneron USA, which is provided with an RF source at the distal end thereof in the form of two electrodes 720. When clear transmitting element

725 of vacuum chamber 705 is made of sapphire, which has electrical insulating properties, the RF waves are prevented from propagating to skin target 735. To allow sapphire to be a suitable transmitting element for apparatus 700, two metallic conducting electrodes 730 are welded in two slits, respectively, formed in the sapphire transmitting element 725. Electrodes 730 are positioned to be within the propagation path of electrodes 720 integrally formed in light source 710. Suitable means, such as a magnetic rod (not shown), may be used to ensure the quick centering of light source 710 with respect to electrodes 730 of sapphire transmitting element 725. During application of the vacuum, skin target 740 contacts the sapphire transmitting element 725 and electrodes 730 transmit RF waves to skin target 740.

[0167] Fig. 19 illustrates an exemplary skin cooling device which is suitable for the pain alleviating apparatus of the present invention. Since the vacuum chamber is configured so as to ensure that a skin target contacts the clear transmitting element when a vacuum is applied, as described hereinabove, skin cooling is optimized when clear transmitting element 1906 is directly cooled. Accordingly, thermally conducting plate 1975, which is cooled by thermoelectric chiller 1979, contacts clear transmitting element 1906, in order to conduct the heat generated by the treated skin target 1960 from the clear transmitting element. The treatment handpiece is provided with chiller 1979 so as to prevent an increase in temperature of the epidermis, which may be damaged if the skin is relatively dark, e.g. Fitzpatrick skin type 4-6. In order to improve the compactness of the skin cooling device, plate 1975 is positioned obliquely with respect to clear transmitting element 1906 without interfering with the propagation of light beam 1908. It will be appreciated that pain alleviation is achieved by application of a vacuum, which brings the skin in contact with the clear transmitting element, and not by means of the chiller. As described in Example 8 hereinbelow, pain relief was noticeable during experimentation performed in conjunction with vacuum-assisted, light-based treatments without employment of a skin chiller.

[0168] The clear transmitting element may be alternatively cooled by applying a low temperature spray, such as produced by Dermachill, USA, to conducting plate 1975 or by means of a chilling liquid flowing over the conducting plate.

[0169] In Fig. 20, apparatus 1990 comprises a thin polycarbonate layer 1994, e.g. having a thickness of 10 microns, attached to the distal face of clear transmitting element 1993 and transparent to the treatment light directed to skin target 1960. Vacuum chamber 1991 is suitably sized and the applied vacuum level is sufficient to draw skin target 1960 to be in pressing contact with polycarbonate layer 1994. Polycarbonate layer 1994 is sufficiently thin to conduct heat from skin target 1960 to clear transmitting element 1993, is sufficiently soft to provide good mechanical matching between skin target 1960 and clear transmitting element 1993, and also provides good optical matching therebetween.

[0170] As described hereinabove, applying a vacuum to the vacuum chamber may either increase or decrease the blood volume fraction within a skin target, depending on a selected configuration of the vacuum chamber. Accordingly, a health professional may employ two differently configured vacuum chambers, each of which is releasably attachable to the same light source handpiece, in order to effect two distinct types of vacuum-assisted light-based treatment, respectively, with a minimum delay to the patient. Thus a single light source and a single vacuum pump may be used for both treatment of vascular lesions by increasing blood concentration within a skin target and for painless hair removal.

[0171] In summation, Table I below tabulates the main differences between prior art vacuum-assisted-light-based treatment methods, by which ablated skin and vaporous debris are evacuated from a skin target, and that of the present invention:

Table I

	Present Invention	Prior Art Smoke Evacuators
<b>Treatment Depth</b>	Subcutaneous	Skin surface
<b>Light source</b>	Non-ablative, 400-1800 nm	Ablative, above 1800 nm
<b>High Vacuum Level (approximately 0 atm)</b>	Yes	No; evacuated air is replaced by fresh air
<b>Automatic Release of Vacuum, to Allow Displacement of Treatment Handpiece</b>	Yes; by means of control unit	Not necessary due to low vacuum level
<b>Contact between Skin and Clear Transmitting Element</b>	Yes; for pain alleviation	No
<b>Suitable for Employment of Gel</b>	Yes	No
<b>Vacuum-Assisted Pain Alleviation</b>	Yes	No
<b>Enhanced Skin Redness</b>	Yes	No

Table continued

	Present Invention	Prior Art Smoke Evacuators
5 Suitable for Non- Ablative IPL and Nd: YAG, Dye, Alexandrite, Ruby, and Diode Lasers	Yes	No; Suitable for Ablative Lasers

10 [0172] Figs. 26A-B illustrate another embodiment of the invention by which a vacuum chamber need not be repositioned from one skin target to another. Fig. 26A is a schematic plan view of the apparatus and Fig. 26B is a cross sectional view thereof. As shown, array 500 of vacuum chambers is embodied by a single flat sheet 505, e.g. disposable and produced from low cost, transparent or translucent molded silicon, which is placed on skin surface 520 and formed with a plurality of vacuum chambers 510. The interior of each vacuum chamber 510 is defined by a bottom which is coplanar with bottom edge 515 of sheet 505, two side walls 522 extending proximally from bottom edge 515, and top edge 522 separated distally from upper surface 525 of sheet 505. A clear transmitting element 540 corresponding to each vacuum chamber 510 is secured to sheet 505, directly above top edge 522 of the vacuum chamber. Clear transmitting element 540 may be an inexpensive thin polycarbonate plate or a diffuser. The bulk material of sheet 505 is also formed with a plurality of conduits 530, each of which in communication with a corresponding vacuum chamber 510 and through which air is evacuated from the corresponding vacuum chamber. The distance between adjacent vacuum chambers 510 is sufficiently small to allow light which has diffused from the interior of each chamber to treat a skin area located underneath a corresponding conduit 530. Each conduit 530 branches into portions 532 and 534, wherein all conduit portions 532 are in communication with a vacuum pump (not shown) and all conduit portions 534 are in communication with a source of compressed air (not shown).

25 [0173] Array 500 advantageously allows a large-area skin surface, such as of an arm or leg, to be treated by a light source. The treatment light source is sequentially directed to each vacuum chamber 510. Following propagation of the light through a selected vacuum chamber in order to treat a corresponding skin target, the light source may be quickly moved or glided to another skin target without having to move a vacuum chamber and overcoming the force which urges it to the skin surface. Since a vacuum chamber is not displaced, gel is similarly not moved and does not accumulate. Consequently, there is no need to provide means for preventing obstruction of gel within the vacuum pump.

30 [0174] Array 500 is also provided with at least one contact detector (not shown), which triggers a signal to activate the vacuum pump. When the contact detector senses the placement of array 500 on a skin surface, the vacuum pump is activated, and the air from all vacuum chambers 510 is evacuated simultaneously. The health professional then sequentially directs the light source to each vacuum chamber 510. Following completion of the treatment for the entire skin surface, the light source is deactivated and then the vacuum pump is deactivated. Alternatively, each vacuum chamber is provided with a contact detector, two control valves to control the passage of fluid through conduits portions 532 and 534, respectively, and light detector (all of which are not shown). When a treatment handpiece is placed on a transmitting element 540, the corresponding contact detector transmits a signal to activate the vacuum pump, open the control valve which regulates the fluid passage through the corresponding conduit portion 532, and then activates the light source. Upon completion of the light treatment, the light source is deactivated after a predetermined period of time or is manually deactivated. The light detector transmits a signal to close the control valve which regulates the fluid passage through the corresponding conduit portion 532 and to open the control valve which regulates the fluid passage through the corresponding conduit portion 534, in order to release the vacuum. This cycle is repeated for all vacuum chambers 510.

#### 45 Example 1

[0175] An experiment was performed to determine the time response of skin erythema following application of a vacuum onto various skin locations. A pipe of 6 mm diameter was sequentially placed on a hand, eye periphery, arm, and forehead at a subatmospheric pressure of approximately 100 millibar. The skin locations were selected based on the suitability for treatment: the hands and eye periphery for wrinkle removal, arm for hair removal, and forehead for port wine stain treatment. The vacuum was applied for the different periods of time of 1/10, 1/2, 1, 2, 3 seconds and then stopped. The erythema level and erythema delay time were then measured.

55 [0176] The response time of the hand and eye periphery was 1/2 sec, the response time of the arm was 1 second and the response time of the forehead was 1/2 second. Accordingly, the experimental results indicate that the necessary delay between the application of the vacuum and firing of the laser or intensified pulsed light is preferably less than 1 second, so as not to delay the total treatment time, since the repetition rate of most laser or intensified pulsed light sources is generally less than 1 pulse /sec.

[0177] The erythema delay time was less than 1 second, and therefore the experimental results indicate that patients



will not sense appreciable aesthetic discomfort following treatment in accordance with the present invention.

### **Example 2**

[0178] An intense pulsed light system comprising a broad band Xe flashlamp and a cutoff filter for limiting light transmission between 755 nm and 1200 nm is suitable for aesthetic treatments, such that light delivered through a rectangular light guide is emitted at an energy density of 20 J/cm<sup>2</sup> and a pulse duration of 40 milliseconds, for hair removal with respect to a treated area of 15 X 45 mm.

[0179] While efficacy of such a light system for the smoothening of fine wrinkles, i.e. photorejuvenation, is very limited by prior art devices, due to the poor absorption of light by blood vessels at those wavelengths, enhanced light absorption in targeted skin structures in accordance with the present invention would increase the efficacy.

[0180] A transparent vacuum chamber of 1 mm height is preferably integrally formed with a handpiece through which intense pulsed light is directed. A diaphragm miniature pump, such as one produced by Richly Tomas which applies a vacuum level of 100 millibar, is in communication with the chamber and a control valve is electronically opened or closed. When the control valve is opened, the pressure in the vacuum chamber is reduced to 100 millibar within less than 10 milliseconds. As a result of the application of vacuum, the skin slightly protrudes into the vacuum chamber at an angle as small as 1/15- 1/45 radian (height divided by size of skin target) and a height of 1 mm. Blood is drawn into the drawn skin target, which achieves a much pinker hue and therefore has a higher light absorbence. The increased redness of the skin increases the light absorption by a factor of 3. As a result, the efficacy of the aforementioned light system is similar to that of a prior art system operating at 60 Joules/cm<sup>2</sup>, which is known to provide adequate results in wrinkle removal procedures. At energy density levels as high as 20 J/cm<sup>2</sup>, it is preferable to chill the epidermis in order to avoid a risk of a burn. Epidermis chilling is accomplished by means of an aluminum plate, which is chilled by a thermoelectric chiller. The plate is in contact with the skin and chills the skin just before the handpiece is moved to the chilled skin target, prior to treatment.

[0181] The invention has thereby converted an intense pulsed light device for hair removal into an efficient photorejuvenation device as well.

### **Example 3**

[0182] An Nd:YAG laser operating at 1064 nm, 40 milliseconds pulse duration, and energy density of 70 J/cm<sup>2</sup> is suitable for prior art hair removal having a spot size of 7 mm. By prior art hair removal, absorption of light in the hair shaft melanin is limited, with a contributory factor in hair removal being attributed to the absorption of light by blood in the hair follicle bulb zone. Since the energy density level of 70 J/cm<sup>2</sup> is risky to the epidermis of dark skin, it would be preferable to operate the laser at 40 J/cm<sup>2</sup>.

[0183] A vacuum chamber is preferably integrally formed with a handpiece through which intense pulsed light is directed, at a distance of 1 mm from the skin target. A vacuum is applied to the skin target for 2 seconds. The blood concentration near the follicle bulb and in the bulge at a depth of 4 and 2 mm, respectively, is increased by a factor of 2. As a result the laser is operated with the same efficacy at energy levels closer to 40 J/cm<sup>2</sup> and is much safer.

### **Example 4**

[0184] A Dye laser emitting light at a wavelength of 585 nm, with a spot size of 5 mm and pulse duration of 1 microsecond, is used by prior art methods for treatment of vascular lesions, such as telangectasia, and port wine stains, at an energy density level ranging from 10-15 J/cm<sup>2</sup> and for the smoothening of wrinkles at an energy density level of 3 -4 J/cm<sup>2</sup>. Some disadvantages of the prior art method are the purpura that is often produced on the skin during vascular treatments and the very large number of treatments (more than 10) which are necessary for the smoothening of wrinkles.

[0185] By applying a controlled vacuum to a vacuum chamber in contact with a skin target, having either a moderate vacuum level of approximately 600 millibar or a vacuum which is modulated at a frequency of 10 Hz for 1 seconds prior to the firing of the laser, the efficacy of the laser is enhanced. Consequently it is possible to treat vascular lesions at 7 J/cm<sup>2</sup> without creating a purpura and to remove wrinkles with a much smaller number of treatments (5).

### **Example 5**

[0186] A prior art diode laser operated at 810 nm or a Dye laser is suitable for treating vascular rich psoriatic skin, wherein the treated area per pulse is approximately 1 cm<sup>2</sup>. By employing a vacuum chamber attached to the distal end of the handpiece of either of these lasers, blood is drawn to the lesion and treatment efficacy is improved. The vacuum may be applied for 2 seconds prior to firing the laser beam.

**Example 6**

[0187] A deep penetrating laser, such as a pulsed diode laser at 940 nm, an Nd:YAG laser, or an intense pulsed light source operating at an energy density of 30 J/cm<sup>2</sup>, is suitable for thermally damaging a gland, when a vacuum chamber is attached to the distal end of the handpiece thereof. When vacuum is applied for a few seconds, e.g. 1-10 seconds, above a gland such as a sweat gland, excessive blood is drawn into the gland. After the pulsed laser beam is directed to the skin, the absorption of the laser beam by the drawn blood generates heat in the gland, which is thereby damaged. It is therefore possible to more efficiently thermally damage glands with a laser or intense pulsed light source when vacuum is applied to the skin.

**Example 7**

[0188] By placing a vacuum chamber on a skin target in accordance with the present invention prior to the firing of an intense pulsed light source, the treatment energy density level for various types of treatment is significantly reduced with respect to that associated with prior art devices. The treatment energy density level is defined herein as the minimum energy density level which creates a desired change in the skin structure, such as coagulation of a blood vessel, denaturation of a collagen bundle, destruction of cells in a gland, destruction of cells in a hair follicle, or any other desired effects.

[0189] The following is the treatment energy density level for various types of treatment performed with use of the present invention and with use of prior art devices:

- a) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a dye laser unit and having a wavelength of 585 nm: 5-12 J/cm<sup>2</sup> (present invention), 10-15 J/cm<sup>2</sup> (prior art);
- b) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a diode laser unit and having a wavelength of 940 nm: 10-30 J/cm<sup>2</sup> (present invention), 30-40 J/cm<sup>2</sup> (prior art);
- c) treatment of vascular lesions with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm: 5-20 J/cm<sup>2</sup> (present invention), 12-30 J/cm<sup>2</sup> (prior art);
- d) treatment of vascular lesions with light emitted from a KPP laser unit manufactured by Laserscope, USA, and having a wavelength of 532 nm: 4-8 J/cm<sup>2</sup> (present invention), 8-16 J/cm<sup>2</sup> (prior art);
- e) photorejuvenation with light emitted from a dye laser unit and having a wavelength of 585 nm: 2-4 J/cm<sup>2</sup> and requiring 6 treatments (present invention), 2-4 J/cm<sup>2</sup> and requiring 12 treatments (prior art);
- f) photorejuvenation with light emitted from an intense pulsed non-coherent light unit and having a wavelength ranging from 570-900 nm: 5-20 J/cm<sup>2</sup> (present invention), approximately 30 J/cm<sup>2</sup> (prior art);
- g) photorejuvenation with a combined effect of light emitted from an intense pulsed non-coherent light unit and having a wavelength ranging from 570-900 nm and of a RF source: 10 J/cm<sup>2</sup> for both the intense pulsed non-coherent light unit and RF source (present invention), 20 J/cm<sup>2</sup> for both the intense pulsed non-coherent light unit and RF source (prior art);
- h) hair removal with light emitted from a Nd:YAG laser unit and having a wavelength of 1604 nm: 25-35 J/cm<sup>2</sup> (present invention), 50-70 J/cm<sup>2</sup> (prior art);
- i) porphyrin-based photodynamic therapy with light emitting diodes delivering blue light (420 nm), orange light (585 nm), or red light (630 nm) for a treatment duration ranging from 10 msec to 10 min: 5-20 J/cm<sup>2</sup> (present invention), 20-30 J/cm<sup>2</sup> (prior art).

**Example 8**

[0190] A vacuum chamber made of polycarbonate having a length of 50 mm, a width of 25 mm, a height of 3 mm, and a clear transmitting element made of sapphire was used during the treatment of unwanted hairs of 5 patients with an intense pulsed light system which emitted energy in the spectral band of 670-900 nm. A thin layer of gel at room temperature having a thickness of 0.5 mm was applied to a skin target. The suction openings had a diameter of 1 mm and were formed in the vacuum chamber walls at a height of 0.5 mm below the clear transmitting element, in order to prevent the obstruction of the openings by gel or by the drawn skin. A small canister serving as a gel trap was provided intermediate to the fluid passage between the vacuum chamber and the vacuum pump, to prevent gel from being drawn to the inlet port of the vacuum pump. A vacuum level of 500 mmHg was generated within the vacuum chamber and caused the skin target to be drawn in contact with the clear transmitting element.

[0191] An intense pulsed light system having a treatment beam length of 40 mm and width of 15 mm was fired with an energy density of 16 - 20 J/cm<sup>2</sup> and a pulse duration of 30-40 milliseconds. One patient underwent a back hair removal treatment, wherein areas of the back were treated as a control without application of a vacuum onto the skin surface and other areas were treated while a vacuum was applied to the skin surface. The other patients underwent a hair

removal treatment on their legs, chest and abdomen such that a vacuum was applied to some areas, while the treatment of an adjacent area was not vacuum assisted, as a control. For all five patients, a skin chiller was not employed.

[0192] Fig. 21 is a photograph which illustrates two back areas 1985 and 1986, respectively, of one of the patients two months after being treated for hair removal. A vacuum was not applied to the skin surface of back area 1985, while a vacuum was applied to the skin surface of back area 1986. As shown, both back areas remained hairless two months after treatment.

[0193] The pain sensation of the patients was categorized into five levels: Level 0 indicating that pain was not felt at all, Level 5 indicating that pain was intolerable after a few laser shots whereby a patient grimaced and uncontrollably reacted after each shot, Level 1 indicating that the treatment was sensed but without pain, and Levels 2, 3, and 4 indicating an increasing level of pain. All of the patients consistently suffered Pain Level 3-5 when a vacuum was not applied, and the pain was alleviated (Level 2) or was completely prevented (Level 1 or 0) when a vacuum was applied. Pain alleviation was found to be dependent on the time delay between the application of the vacuum and the firing of the intense pulsed light. Pain alleviation was sensed when the intense pulsed light was fired at least 1.5 seconds after application of the vacuum onto the skin surface.

### **Example 9**

[0194] A patient undergoing a hair removal treatment was tested for pain sensitivity. An intense pulsed Diode laser (Light Sheer, Lumenis) operating at 810 nm was employed. A vacuum chamber made of polycarbonate having a length of 40 mm, a width of 15 mm, a height of 3 mm, and a clear transmitting element made of sapphire was used. A thin layer of gel at room temperature having a thickness of 0.5 mm was applied to a skin target. The suction openings had a diameter of 1 mm and were formed in the vacuum chamber walls at a height of 0.5 mm below the clear transmitting element. A small canister serving as a gel trap was provided intermediate to the fluid passage between the vacuum chamber and the vacuum pump, to prevent gel from being drawn to the inlet port of the vacuum pump.

[0195] When a vacuum was not applied to the skin target and the light source operated at an energy density of 42 J/cm<sup>2</sup> and a pulse duration of 30 milliseconds, the patient sensed a Pain Level of 5. When a vacuum level of 500 mmHg was generated within the vacuum chamber causing the skin target to be drawn in contact with the clear transmitting element and the light source operated at an energy density of 42 J/cm<sup>2</sup> and a pulse duration of 30 milliseconds, the patient sensed a considerably reduced Pain Level of 2. This reduced pain level during the vacuum assisted treatment was found to be equivalent to the mild pain sensed when the light source operated at an energy density of only 26 J/cm<sup>2</sup> and a pulse duration of 30 milliseconds and a vacuum was not applied to the skin target.

[0196] While some embodiments of the invention have been described by way of illustration, it will be apparent that the invention can be carried into practice with many modifications, variations and adaptations, and with the use of numerous equivalents or alternative solutions that are within the scope of persons skilled in the art, without departing from the spirit of the invention or exceeding the scope of the claims.

### **Claims**

1. An apparatus for vacuum-assisted light-based skin treatments, comprising:
  - a) a non-ablative intense pulsed monochromatic or non-coherent light source;
  - b) a vacuum chamber placeable on a skin target which has an opening on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to light generated by said source and directed to said skin target;
  - c) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said opening; and
  - d) means for preventing influx of air into vacuum chamber during a vacuum applying mode.
2. The apparatus according to claim 1, wherein the vacuum applying means comprises a vacuum pump.
3. The apparatus according to claim 2, wherein the vacuum applying means further comprises at least one control valve and control means for controlling operation of the vacuum pump, the at least one control valve, and the light source, said control means being suitable for firing the light source after a first predetermined delay ranging from approximately 0.5 sec to approximately 4 seconds following operation of the vacuum pump, for increasing the pressure in the vacuum chamber to atmospheric pressure following deactivation of the light source to allow for effortless repositioning of the vacuum chamber to a second skin target, for verifying that a desired energy density level of the light is being directed to the skin target, and for deactivating the light source if the energy density level

is significantly larger than said desired level, said control means being selected from the group of electronic means, pneumatic means, electrical means, and optical means and being actuated by means of a finger depressable button positioned on a light treatment handpiece.

- 5     **4.** The apparatus according to claim 1, wherein influx of air into the vacuum chamber during a vacuum applying mode is prevented by means of a control valve and control circuitry.
- 10    **5.** The apparatus according to claim 1, wherein the wavelength of the light ranges from 400 to 1800 nm, the pulse duration of the light ranges from 10 nanoseconds to 900 msec, the energy density of the light ranges from approximately 2 to approximately 150 J/ cm<sup>2</sup>, and the level of applied vacuum within the vacuum chamber ranges from approximately 0 to approximately 1 atmosphere.
- 15    **6.** The apparatus according to claim 1, wherein the vacuum chamber is connected to, or integrally formed with, a proximately disposed handpiece through which light propagates towards the skin target, and the vacuum chamber optionally has a proximate cover formed with an aperture which is attachable to a handpiece having an integral clear transmitting element.
- 20    **7.** The apparatus according to claim 5, wherein the light source is selected from the group of Dye laser, Nd:YAG laser, Diode laser, light emitting diode, Alexandrite laser, Ruby laser, Nd:YAG frequency doubled laser, Nd:Glass laser, a non-coherent intense pulse light source, and and a non-coherent intense pulse light source combined with an RF source, the light is suitable for hair removal, collagen contraction, photorejuvenation, treatment of vascular lesions, treatment of sebaceous or sweat glands, treatment of warts, treatment of pigmented lesions, treatment of damaged collagen, treatment of acne, treatment of warts, treatment of keloids, treatment of sweat glands, and treatment of psoriasis, and the vascular lesions are selected from the group of port wine stains, telangiectasia, rosacea, and spider veins.
- 25    **8.** The apparatus according to claim 1, wherein the clear transmitting element is separated from the adjoining skin surface by a gap ranging from 0.5 to 50 mm and is suitable for transmitting the light in a direction substantially normal to a skin surface adjoining the skin target.
- 30    **9.** The apparatus according to claim 1, wherein the vacuum chamber has at least one suction opening and is provided with a rim for sealing the peripheral contact area between the skin surface adjoining the skin target and a vacuum chamber wall, the vacuum being applied to the vacuum chamber via said at least one suction opening.
- 35    **10.** The apparatus according to claim 1, wherein the vacuum chamber is U-shaped.
- 40    **11.** The apparatus according to claim 3, wherein the increase in vacuum chamber pressure is triggered by means of a light detector which transmits a signal to the control means upon sensing a significant decrease in optical energy generated by the light source or after a second predetermined delay, following deactivation of the light source.
- 45    **12.** The apparatus according to claim 1, wherein the width of a treatment spot per pulse of the light is greater than 5 mm or ranges from 15 to 50 mm.
- 50    **13.** The apparatus according to claim 2, wherein the vacuum pump is a peristaltic pump for drawing air and gel from the interior of the vacuum chamber via a hose connected to a conduit in communication with the interior of the vacuum chamber or is an air pump.
- 55    **14.** The apparatus according to claim 3, further comprising a skin contact detector for sensing the placement of the vacuum chamber onto the skin target and for generating a first signal to activate the vacuum pump following placement of the vacuum chamber onto the skin target, wherein the control valve is opened following generation of a second signal by means of a light detector which is adapted to sense termination of the light directed to the skin target, atmospheric pressure air thereby being introduced to the interior of the vacuum chamber, said second signal also being suitable for deactivating the vacuum pump.
- 60    **15.** The apparatus according to claim 2, further comprising an array of vacuum chambers placeable on a skin surface, wherein said array is formed from a single sheet made of material which is transparent or translucent to the light, said sheet is formed with a plurality of conduits for air evacuation such that each of said conduits is in communication with a corresponding vacuum chamber, the distance between adjacent vacuum chambers is sufficiently small to

allow light which has diffused from the interior of each chamber to treat a skin area located underneath a corresponding conduit, and each conduit branches into first and second portions which are in communication with the vacuum pump and with a source of compressed air, respectively.

5 16. The apparatus according to claim 15, wherein each vacuum chamber is provided with a contact detector for triggering a signal to activate the vacuum pump, two control valves to control the passage of fluid through the corresponding first and second conduits portions, respectively, and a light detector which generates a signal to introduce compressed air through the corresponding second conduit portion upon sensing the termination of the light directed to the skin target or the first conduit portions are arranged such that the air from all vacuum chambers is evacuated simultaneously upon activation of the vacuum pump.

10 17. The apparatus according to claim 1, wherein the vacuum applying means comprises:

- a) a vertically displaceable cover to which the clear transmitting element is secured;
- 15 b) chamber walls which surround, and are of a similar shape as, said cover, a vacuum being generated within a vacuum chamber defined by the volume between said cover, said walls, and the skin target upon proximal displacement of said cover relative to said walls; and
- c) an aeration tube for introducing atmospheric air to the vacuum chamber during a vacuum release mode, said aeration tube being in communication with a valve which is actuated upon conclusion of a skin target treatment,

20 wherein the means for preventing influx into the vacuum chamber is a sealing element which is secured to the outer periphery of the cover and resiliently contacts the chamber walls, wherein a proximally directed force or distally directed force is generated by any means selected from the group of a plurality of solenoids, a spring assembly, and a pneumatic device, or a combination thereof, which are deployed around the periphery of the cover and connected to the walls,

25 wherein the proximally directed force is controllable so as to adjust the height of the drawn skin target relative to the adjoining skin surface and is optionally supplemented by means of a vacuum pump.

30 18. The apparatus according to claim 17, wherein the solenoids are energized by a 1.5 V battery.

35 19. The apparatus according to any of claims 1 to 14, further comprising means for preventing passage of skin cooling gel to the vacuum applying means which comprises a trap, a first conduit through which gel and air are drawn from the vacuum chamber to said trap, a second conduit through which air is drawn from said trap to the vacuum pump, and optionally a filter at the inlet of said first and second conduits; a detachable vacuum chamber upper portion having an open central area, a clear transmitting element attached to said upper portion, vacuum chamber walls, a vacuum chamber cover perpendicular to said walls and suitably sized so as to support said upper portion, and a plurality of attachment clips pivotally connected to a corresponding vacuum chamber wall for detachably securing said upper portion to said vacuum chamber cover, detachment of said upper portion allowing removal of gel retained within the vacuum chamber interior; a hydrophobic material to which vacuum chamber walls are coated; or a vacuum chamber configured such that at least one suction opening is sufficiently spaced above the distal end of a vacuum chamber wall and from the centerline of the vacuum chamber so as to prevent obstruction of the at least one suction opening by gel and drawn skin upon application of the vacuum.

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45 20. The apparatus according to claim 19, wherein the trap is suitable for the introduction therein of an ion exchange resin with which the gel is boundable.

50 21. The apparatus according to claim 19, comprising indication means that the skin target has undergone a light-based treatment by means of gel which is discharged from an end of the hose onto a skin surface during a vacuum applying mode or by means of gel which falls to the skin surface during a vacuum release mode in the shape of the distal end of the vacuum chamber walls.

55 22. The apparatus according to any of claims 1 to 18, further comprising means for skin cooling, said skin cooling means being adapted to reduce the rate of temperature increase of the epidermis at the skin target and the level of the applied vacuum being suitable for evacuating condensed vapors which are produced within the gap between the clear transmitting element and the skin target and condense on the clear transmitting element during the cooling of skin, wherein the skin cooling means is a metallic plate positionable on the skin surface adjoining the skin target and in abutment with the vacuum chamber on the external side thereof or in contact with the clear transmitting element,

said plate being cooled by means of a thermoelectric cooler; a polycarbonate layer transparent to the directed light which is attached to the distal face of the clear transmitting element; or a gel, a low temperature liquid or gas applied onto the skin target.

- 5     **23.** The apparatus according to any of claims 1 to 18, wherein the apparatus is suitable for alleviating or preventing pain caused by a non-ablative light-based treatment of a targeted skin structure, wherein the gap separating the clear transmitting element from the skin surface adjoining the skin target and the magnitude of the proximally directed force resulting from the applied vacuum in combination are suitable for drawing the skin target to the vacuum chamber via the opening on the distal end of the vacuum chamber until the skin target  
10     contacts the clear transmitting element for a duration equal to the first predetermined delay, whereby pain signals generated by the nervous system during the treatment of the skin structure are alleviated or prevented, wherein the control means is suitable for firing the light source after the first predetermined delay, following operation of the vacuum applying means, and is suitable for controlling the vacuum level generated by the vacuum applying means,  
15     wherein the control means has a plurality of finger depressable buttons, each of which being adapted to set the vacuum applying means and light source at a unique combination of operating conditions so as to generate a predetermined vacuum level within the vacuum chamber and to fire the light source after a predetermined time delay following the operation of the vacuum applying means.
- 20     **24.** The apparatus according to any of claims 1 to 18, further comprising means to stabilize the vacuum chamber on a substantially non-planar skin surface.
- 25     **25.** The apparatus according to any of claims 1 to 22 and 24, wherein the vacuum chamber has at least one support element suitable for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of the skin target and is releasably attachable to a treatment light handpiece.
- 30     **26.** The apparatus according to any of claims 1 to 25, wherein the vacuum chamber is one-hand graspable by means of a handle connected thereto.
- 35     **27.** An apparatus for controlling the depth of light absorption by blood vessels under a skin surface, comprising:  
a) a vacuum chamber placed on a skin target which is formed with an aperture on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to intense pulsed monochromatic or non-coherent light directed to said skin target and suitable for transmitting the light in a direction substantially normal to a skin surface adjoining said skin target;  
b) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said aperture; and  
c) means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target, optical energy associated with the directed light being absorbed within said predetermined depth and suitable for thermally injuring or treating predetermined skin structures located at said depth.
- 40     **28.** The apparatus according to claim 27, wherein the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is a means for modulating the applied vacuum.
- 45     **29.** The apparatus according to claim 27, wherein the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is at least one support element positioned at a skin area adjoining the skin target and having a thickness suitable for inducing an increase in the concentration of blood and/or blood vessels within said predetermined depth, and optionally comprising at least one leg having a thickness considerably less than the at least one support element and positioned at the periphery of the vacuum chamber, said at least one leg being separated from an adjacent support element, the at least one support element being adapted to urge blood expelled by said at least one leg towards the skin target.
- 50     **30.** The apparatus according to claim 27, which is suitable for drawing the skin target approximately 1 mm from the adjoining skin surface, wherein the maximum protrusion of the drawn skin from the adjoining skin surface is limited by the clear transmitting element.
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31. The apparatus according to claim 28, wherein the frequency of vacuum modulation ranges from 0.2 to 100 Hz.
32. The apparatus according to claim 27, further comprising a control unit for controlling operation of the vacuum applying means and light source, for controlling operation of at least one control valve in communication with the vacuum chamber, for firing the light after a predetermined delay ranging from approximately 10 msec to approximately 1 second following application of the vacuum, and for electronically modulating the vacuum.
33. The apparatus according to claim 27, wherein the duration of vacuum application to the vacuum chamber is less than 2 seconds.
34. The apparatus according to claim 27, wherein the light emitted from the light source has any wavelength band from 400 nm to 1800 nm,  
 wherein the treatment energy density level for treatment of vascular lesions, port wine stains, telangectasia, rosacea, and spider veins with light emitted from a dye laser unit and having a wavelength of 585 nm ranges from 5 to 12 J/cm<sup>2</sup>,  
 wherein the treatment energy density level for treatment of vascular lesions, port wine stains, telangectasia, rosacea, and spider veins with light emitted from a diode laser unit and having a wavelength of 940 nm ranges from 10 to 30 J/cm<sup>2</sup>,  
 wherein the treatment energy density level for treatment of vascular lesions with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570 to 900 nm ranges from 5 to 20 J/cm<sup>2</sup>,  
 wherein the treatment energy density level for photorejuvenation with light emitted from a dye laser unit and having a wavelength of 585 nm ranges from 1 to 4 J/cm<sup>2</sup>,  
 wherein the treatment energy density level for photorejuvenation with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570 to 900 nm ranges from 5 to 20 J/cm<sup>2</sup>,  
 wherein the treatment energy density level for photorejuvenation with a combined effect of light emitted from an intense pulsed non-coherent light unit and having a wavelength ranging from 570 to 900 nm and of a RF source is approximately 10 J/cm<sup>2</sup> for both the intense pulsed non-coherent light unit and RF source,  
 wherein the treatment energy density level for hair removal with light emitted from a Nd:YAG laser unit and having a wavelength of 1604 nm ranges from 25 to 35 J/cm<sup>2</sup>,  
 wherein the treatment energy density level for porphyrin-based photodynamic therapy with light emitting diodes delivering light at a wavelength of 420 nm, 585 nm, or 630 nm ranges from 5 to 20 J/cm<sup>2</sup>.
35. The apparatus according to any of claims 27 to 34, further comprising a pulsed radio frequency (RF) source for directing suitable electromagnetic waves at a frequency ranging from 0.2 to 10 MHz to the skin target,  
 wherein the RF source is a bipolar RF generator which generates alternating voltage applied to the skin surface via wires and electrodes or is a monopolar RF generator,  
 wherein the control unit is suitable for transmitting a first command pulse to the at least one control valve and a second command pulse to both the light source and RF source.
36. The apparatus according to claim 32, further comprising an erythema sensor for measuring the degree of skin redness induced by the vacuum applying means, wherein the control unit is suitable for controlling, prior to firing the light source, the energy density of the light emitted from the light source, in response to the output of the erythema sensor.
37. The apparatus according to claim 32, further comprising a skin contact detector for sensing the placement of the vacuum chamber onto the skin target, the control unit being suitable for activating the vacuum applying means in response to a signal transmitted by said skin contact detector.
38. The apparatus according to claim 32, further comprising a light detector for sensing the termination of the light directed to the skin target, the control unit being suitable for regulating a control valve in response to a signal transmitted by said light detector so as to introduce atmospheric pressure air to the interior of the vacuum chamber.
39. The apparatus according to claim 27, further comprising an array of vacuum chambers placeable on a skin surface, wherein the array is formed from a single sheet made of material which is transparent or translucent to the light, said sheet being formed with a plurality of conduits for air evacuation such that each of said conduits is in communication with a corresponding vacuum chamber.
40. The apparatus according to any of claims 27 to 39, further comprising means for skin cooling, said skin cooling means adapted to reduce the rate of temperature increase of the epidermis at the skin target.

41. The apparatus according to any of claims 27 to 39, further comprising means for preventing passage of skin cooling gel to the vacuum applying means.

5 42. The apparatus according to any of claims 27 to 41, wherein the vacuum chamber is releasably attachable to a treatment light handpiece.

43. The apparatus according to any of claims 27 to 42, wherein the vacuum chamber is one-hand graspable by means of a handle connected thereto.

10 44. The apparatus according to any of claims 27 to 43, further comprising means to stabilize the vacuum chamber on a substantially non-planar skin surface.

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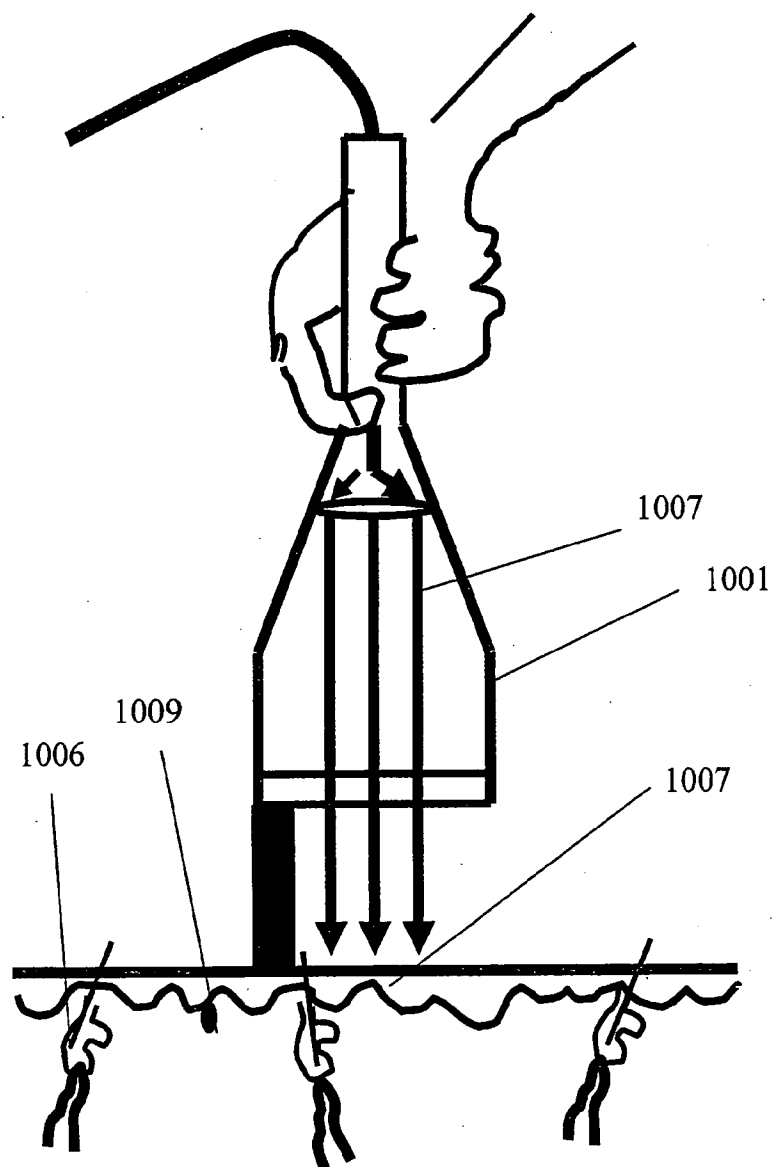


Fig. 1

PRIOR ART

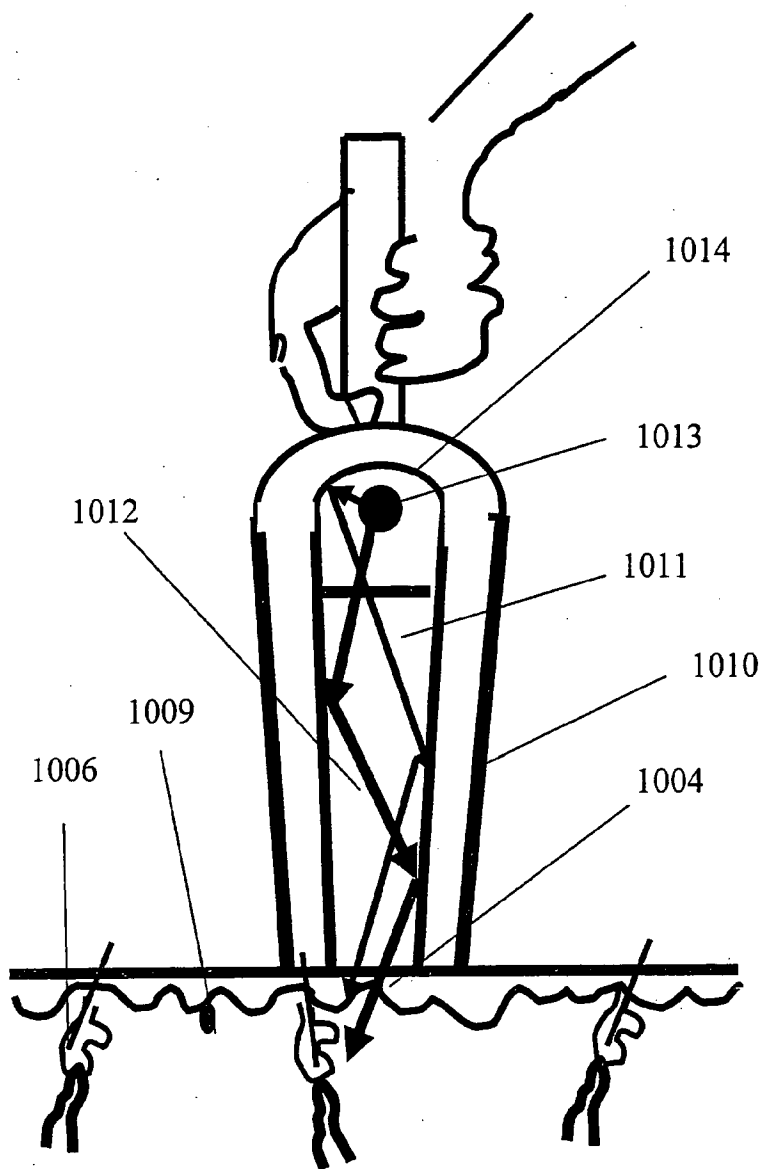


Fig. 2  
PRIOR ART

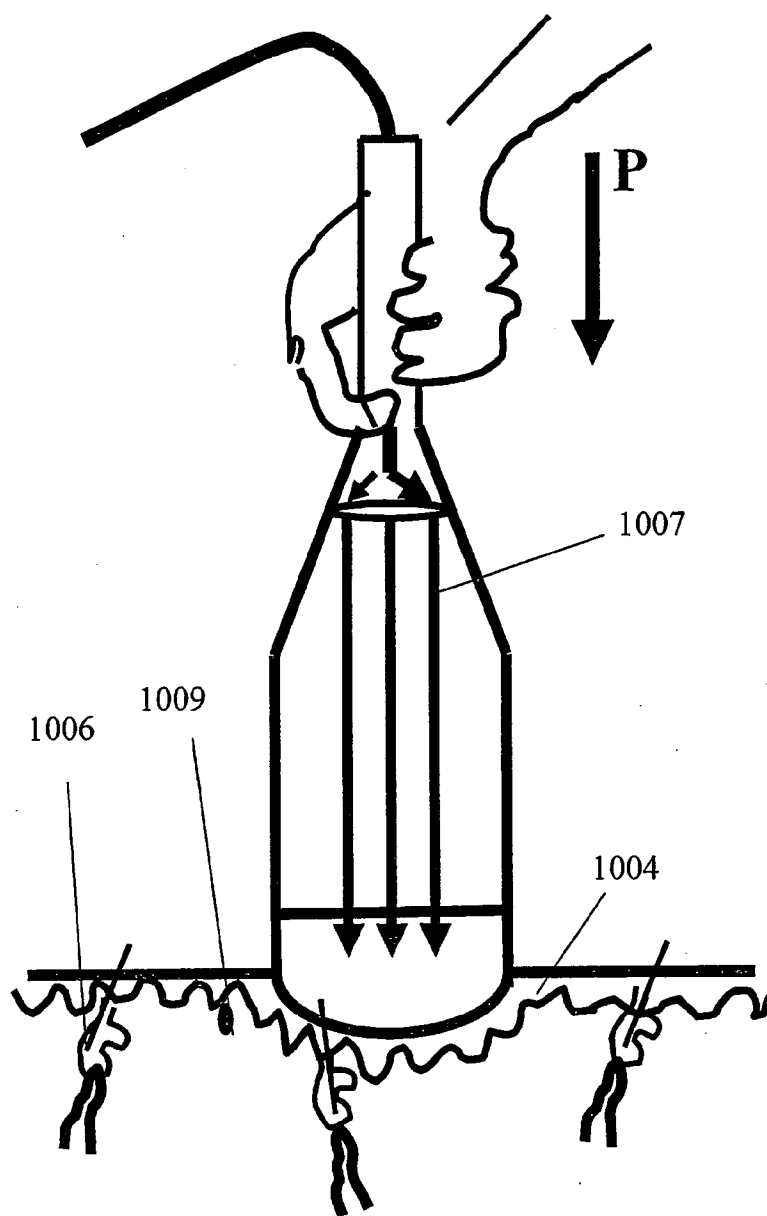


Fig. 3  
PRIOR ART

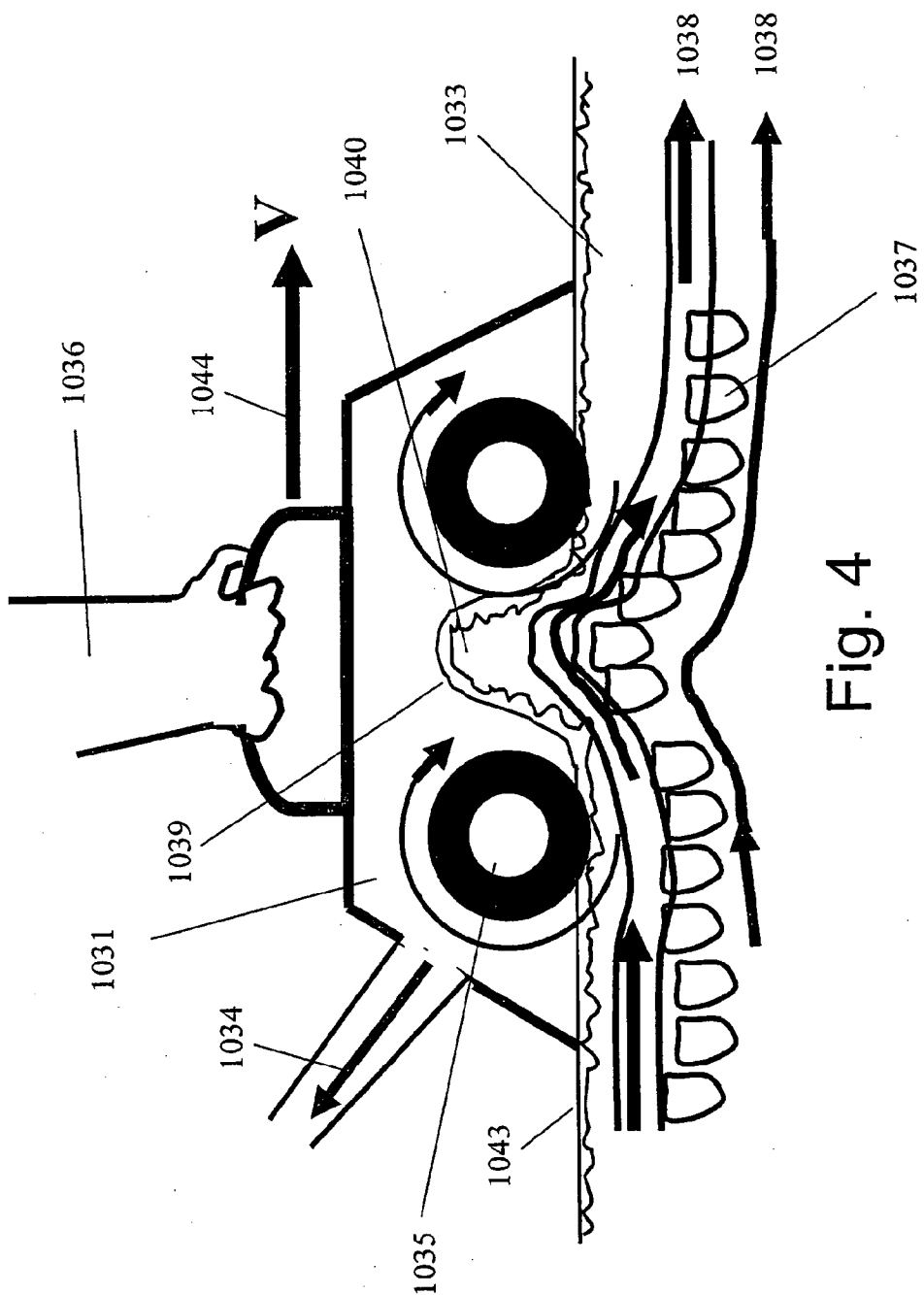


Fig. 4  
PRIOR ART

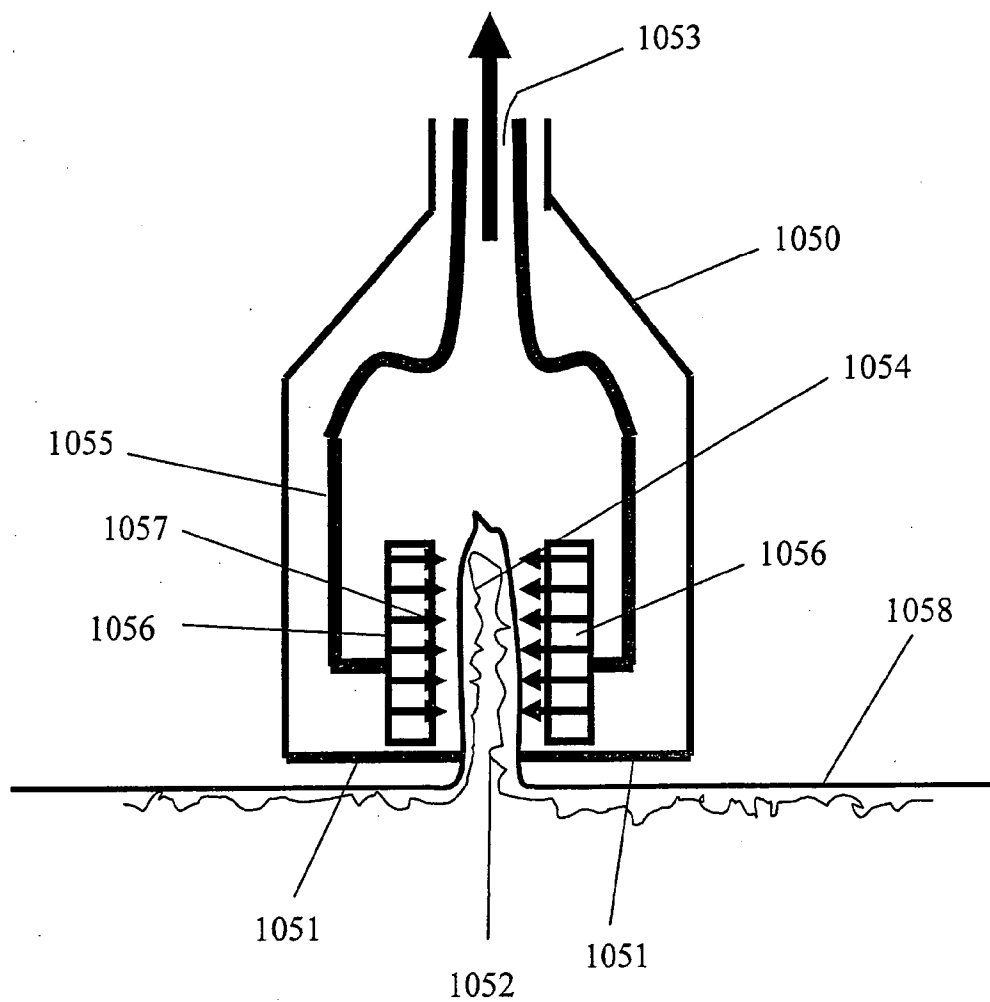
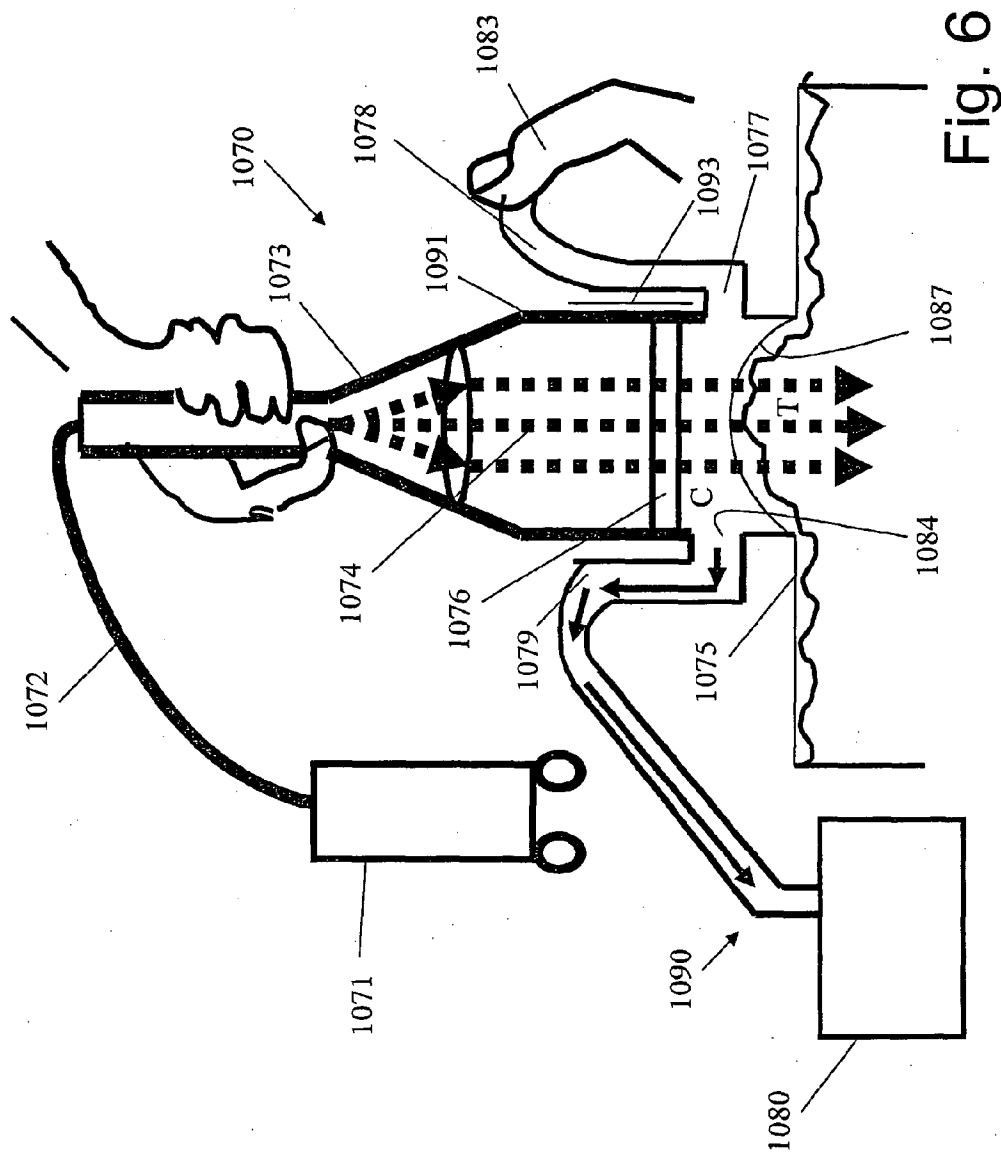


Fig. 5  
PRIOR ART



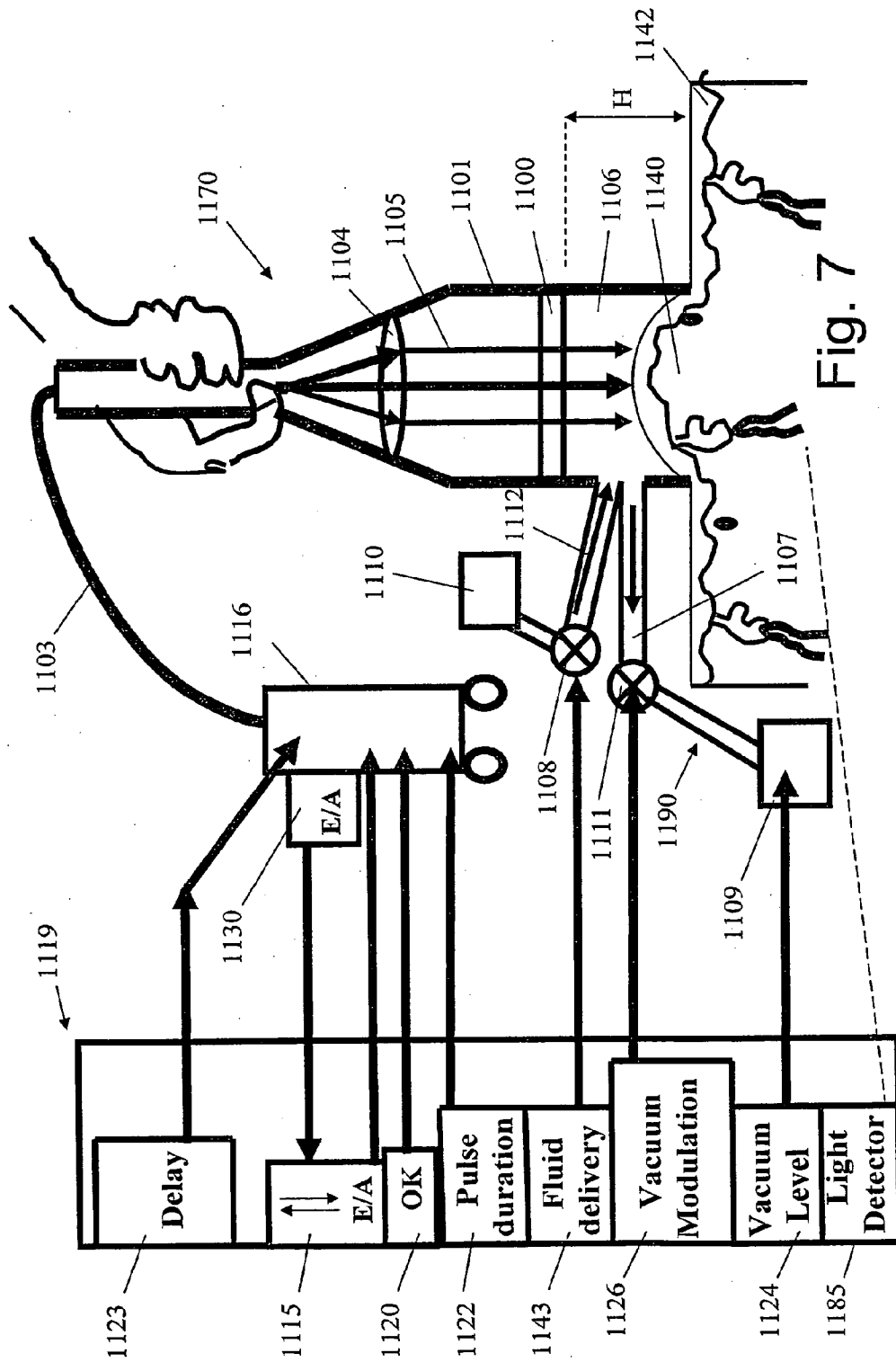


Fig. 7

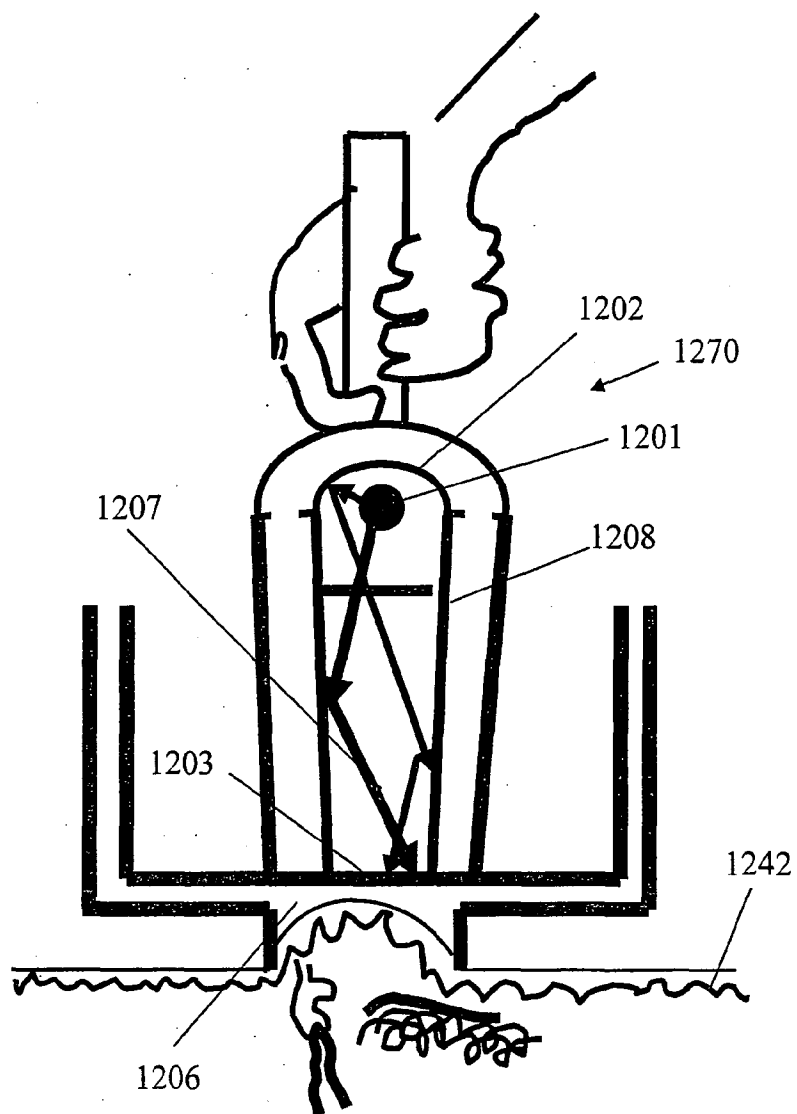


Fig. 8



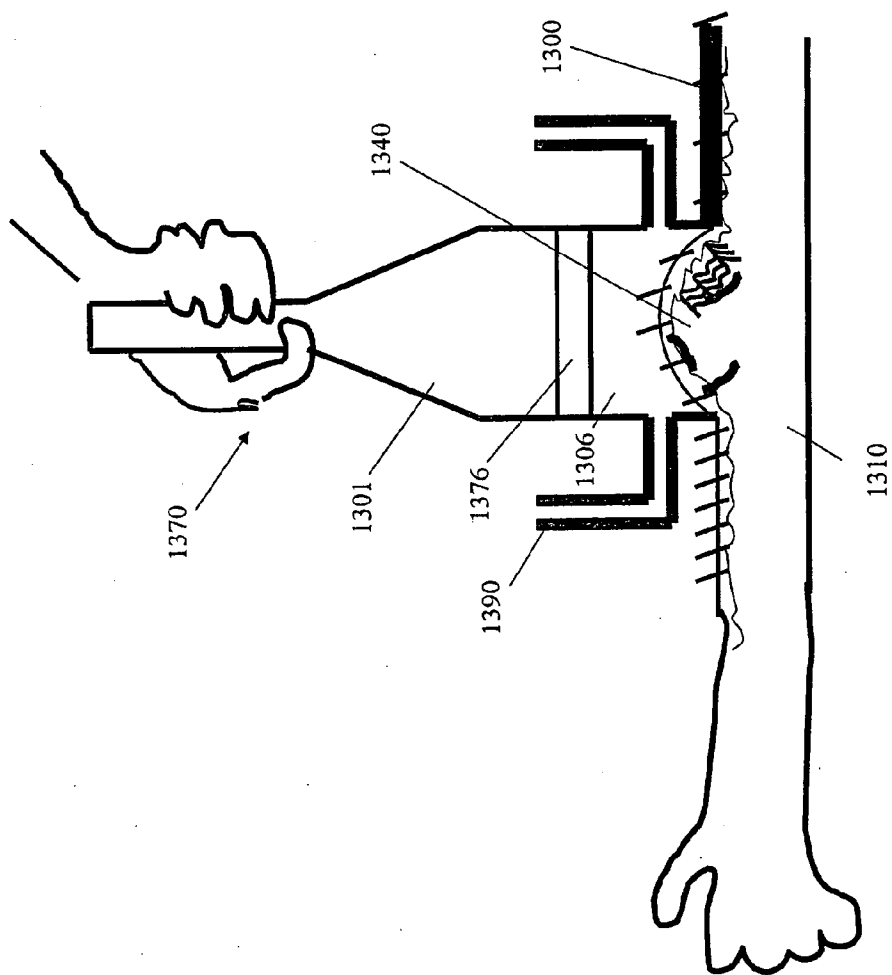
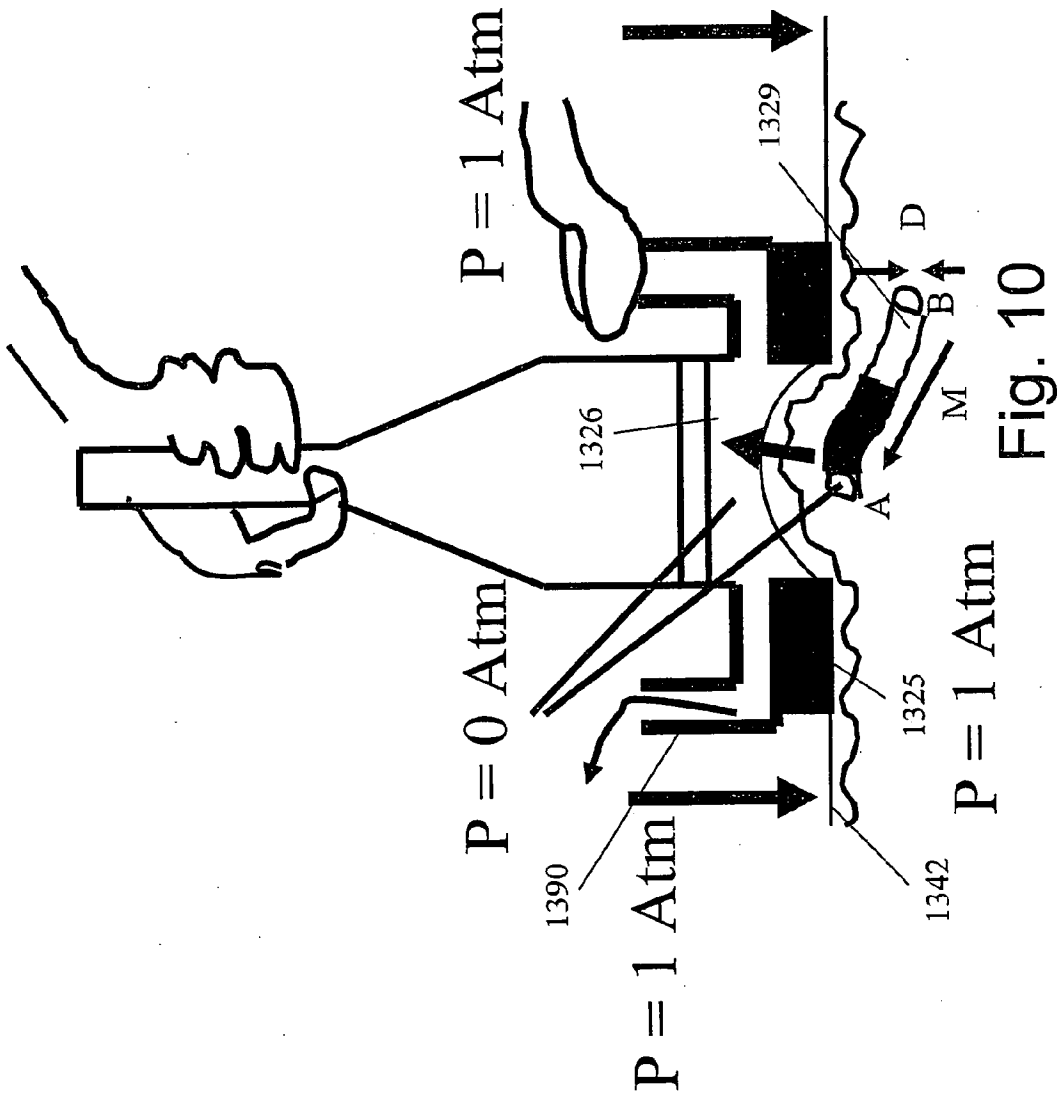


Fig. 9



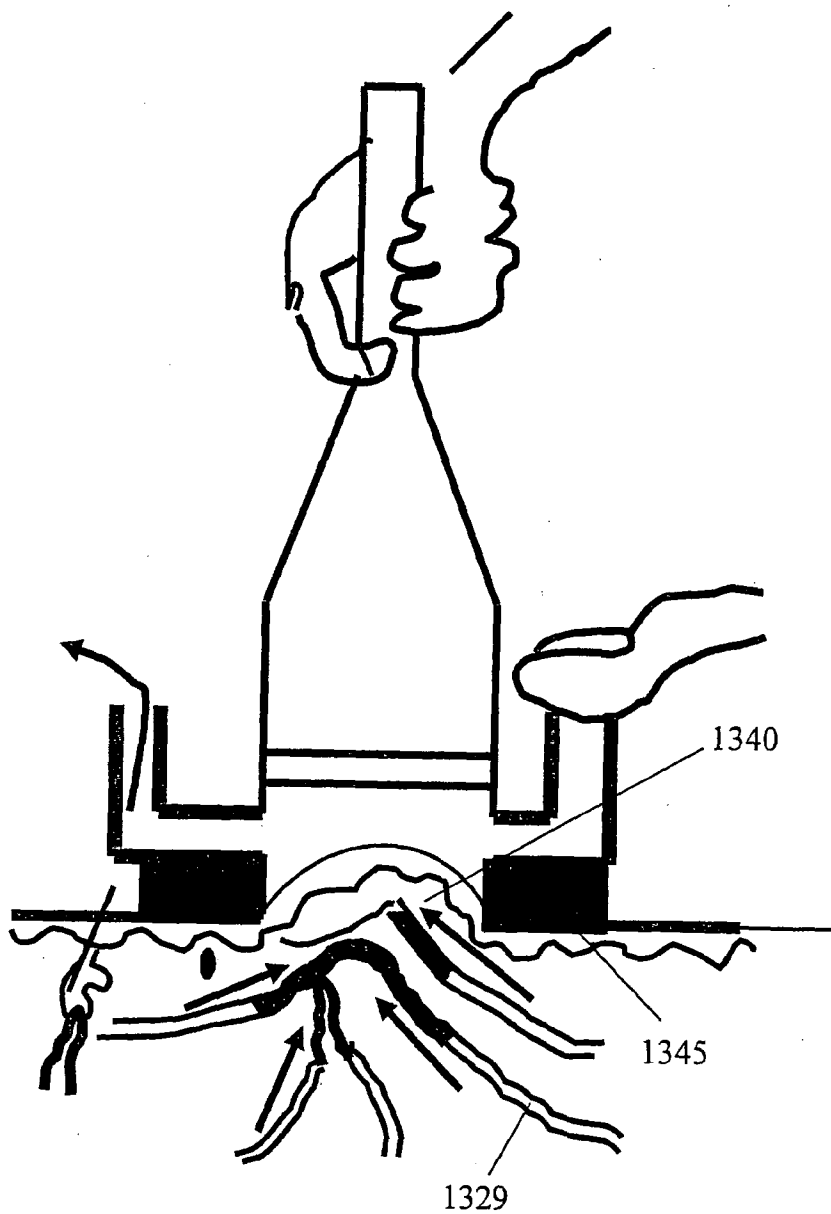


Fig. 11

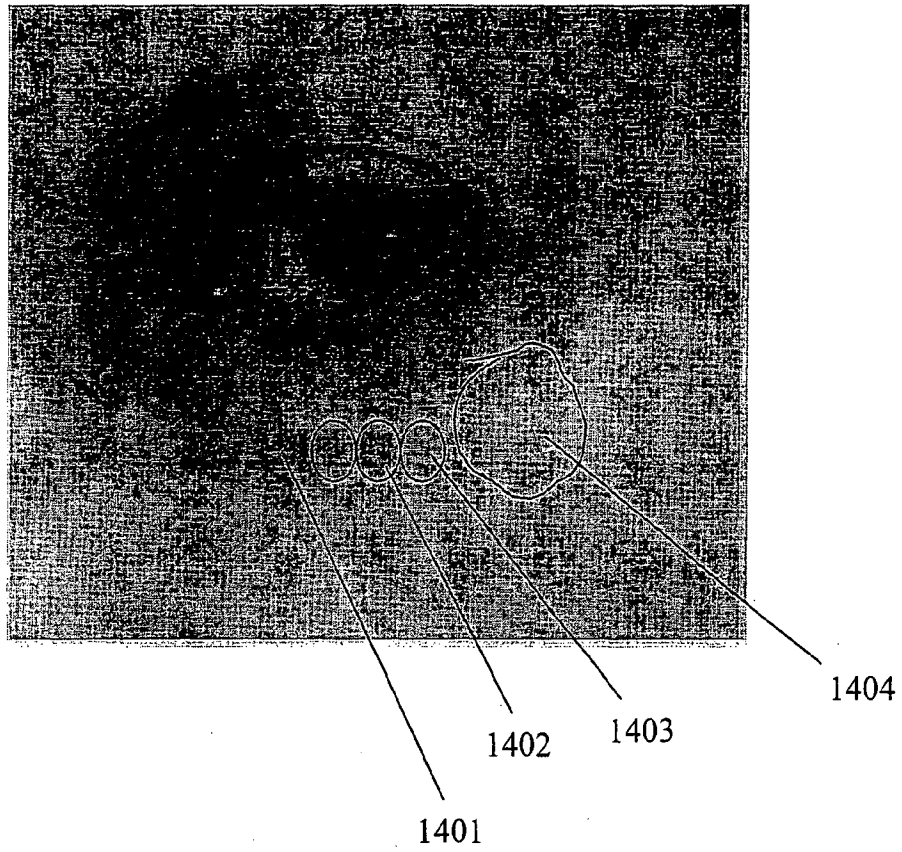
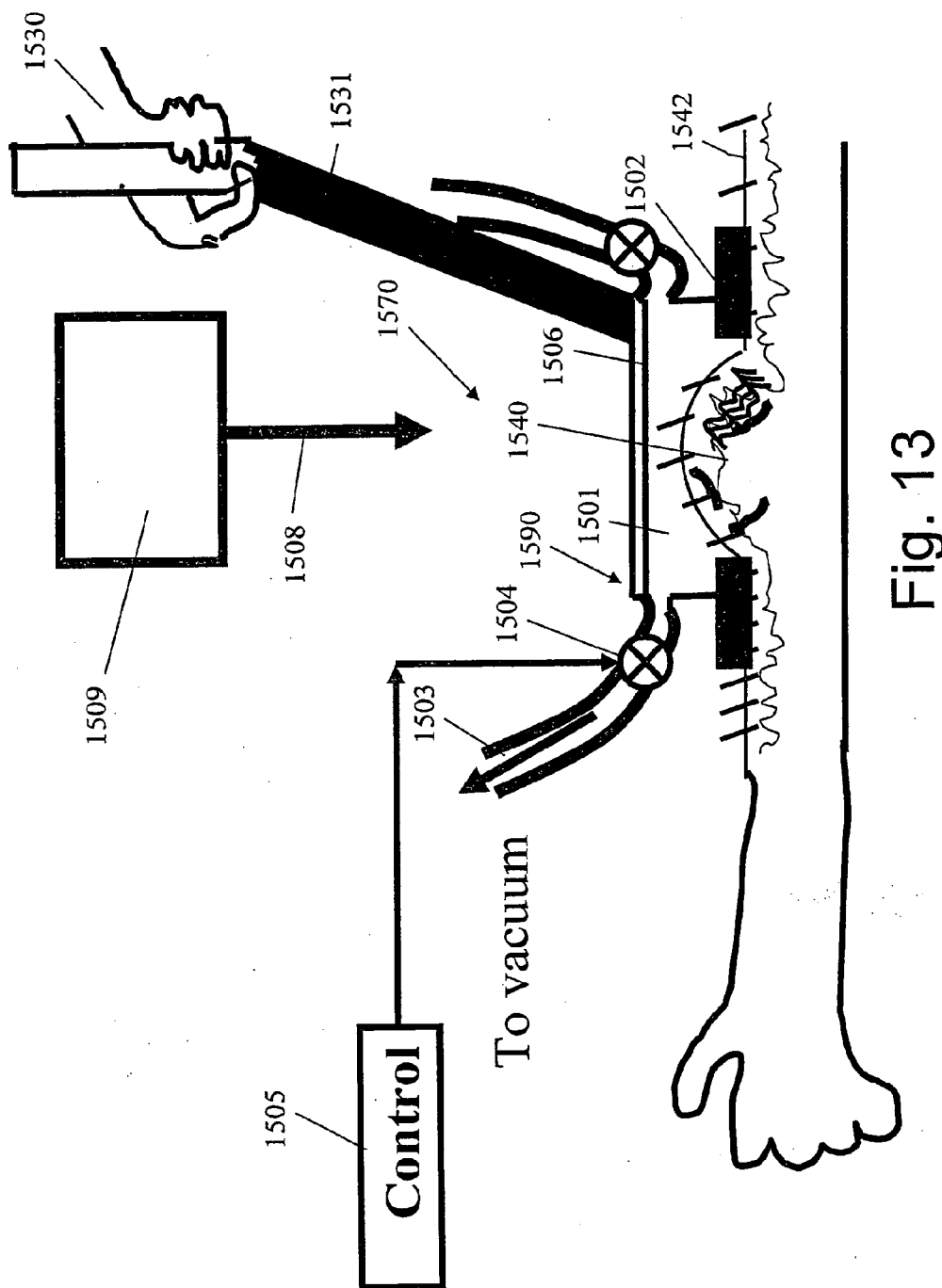


Fig. 12



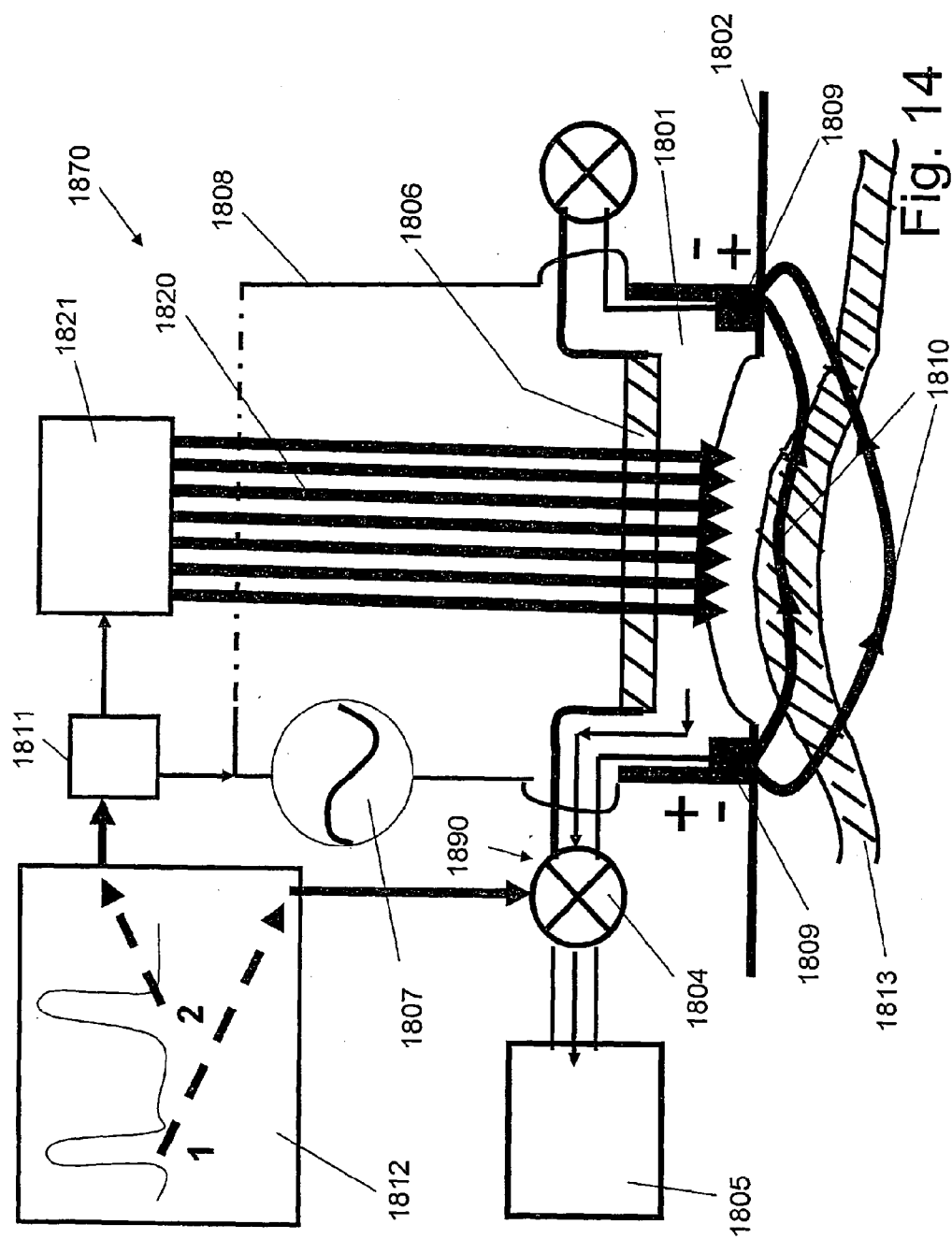
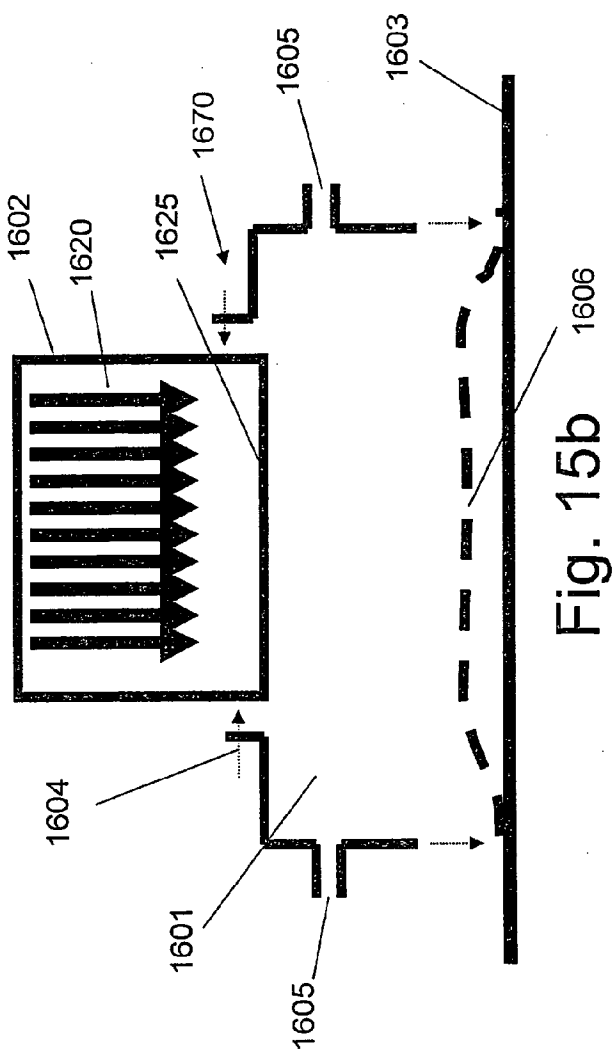
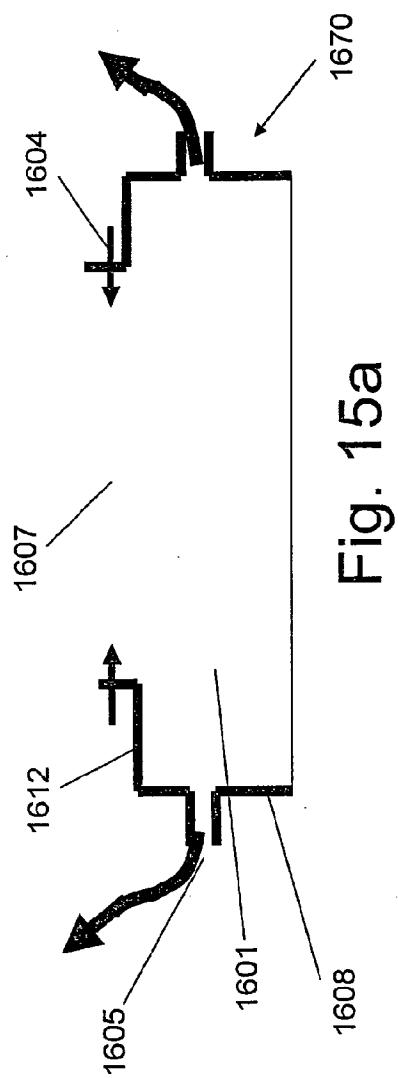


Fig. 14



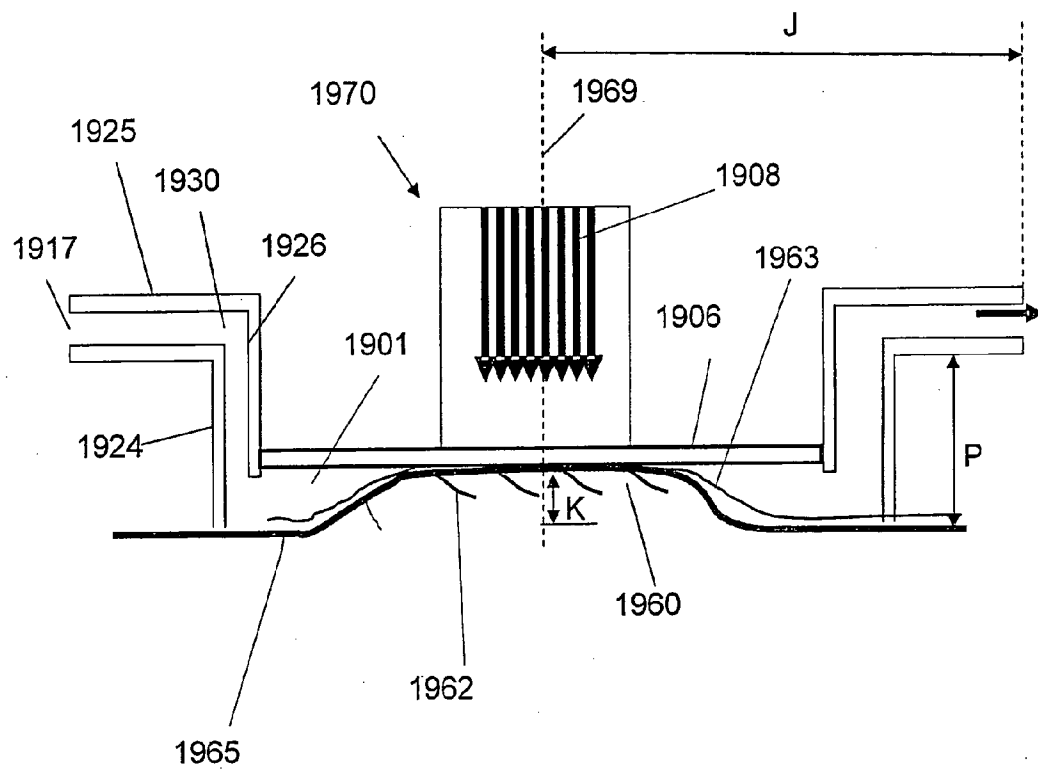


Fig. 16



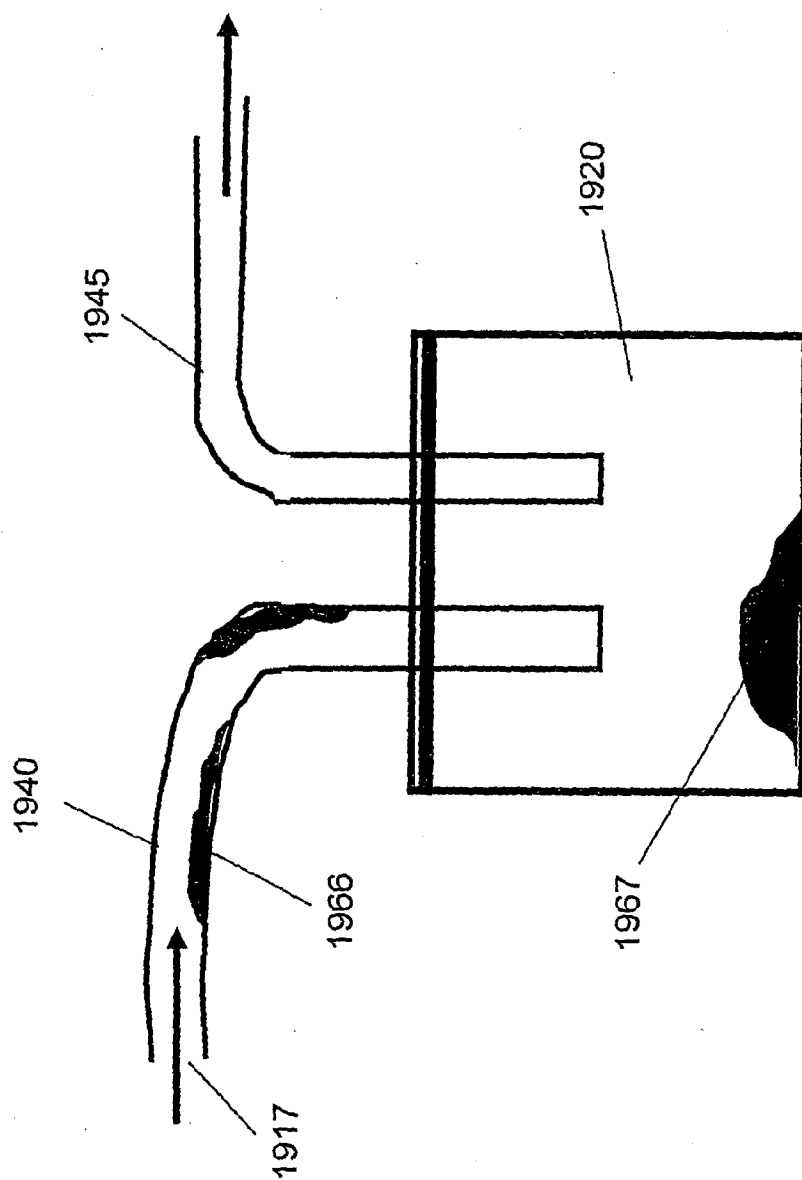


Fig. 17

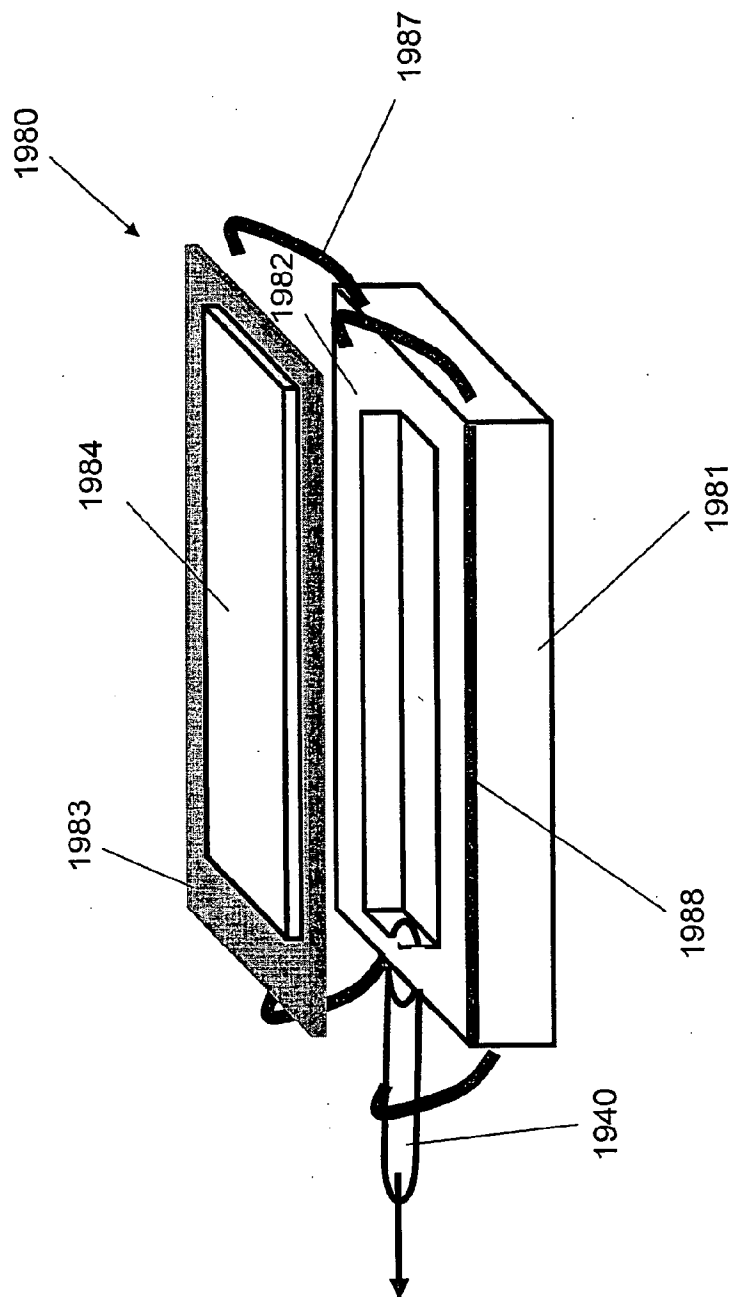


Fig. 18

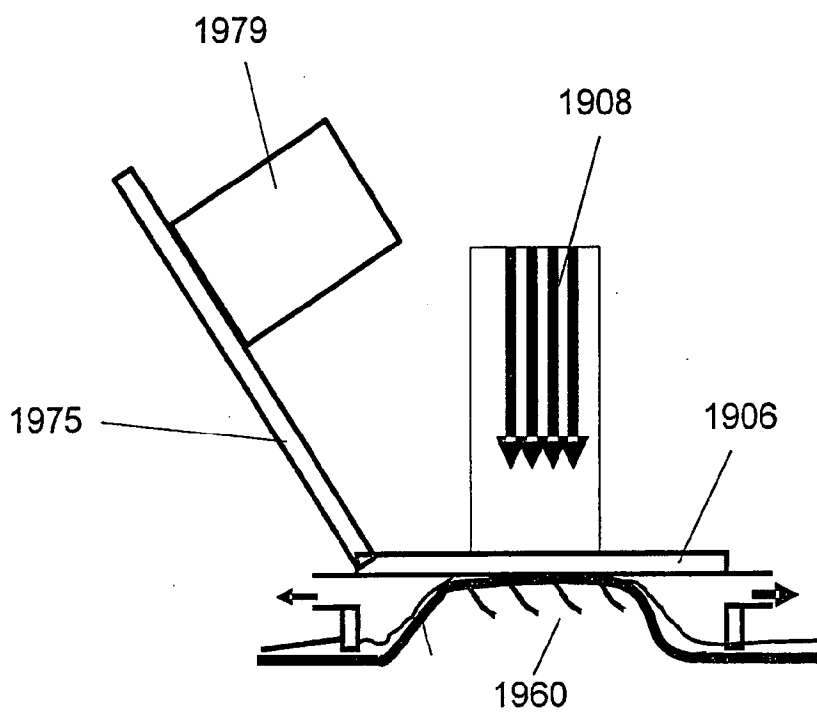


Fig. 19

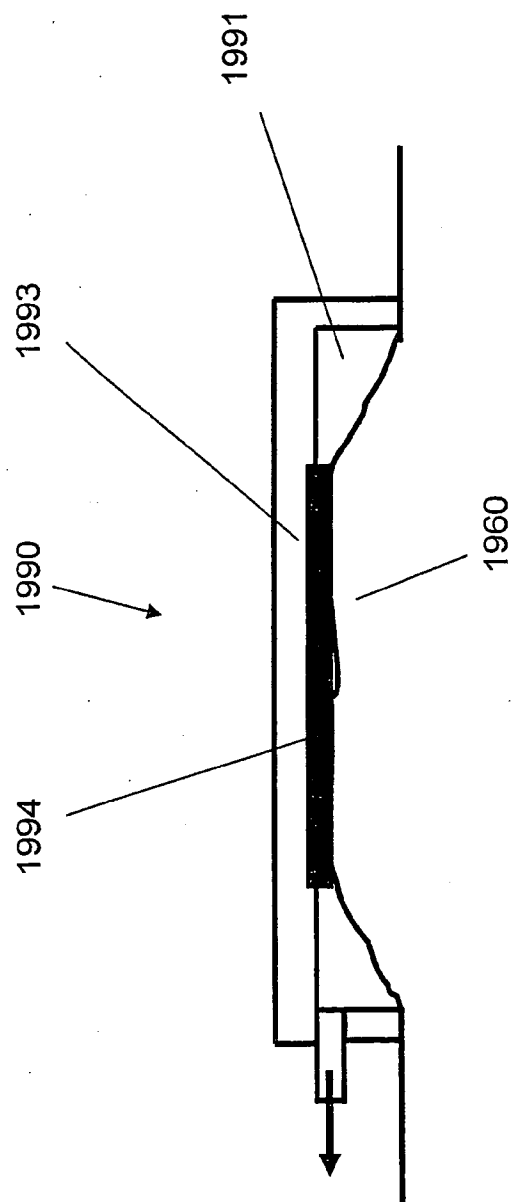


Fig. 20

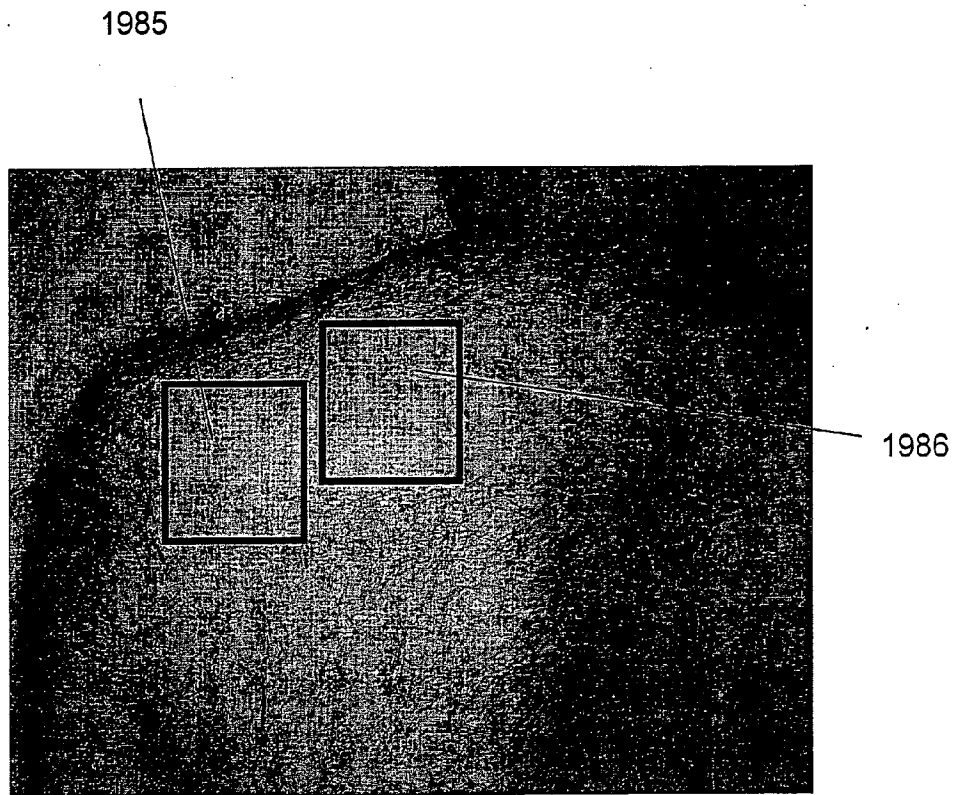


Fig. 21

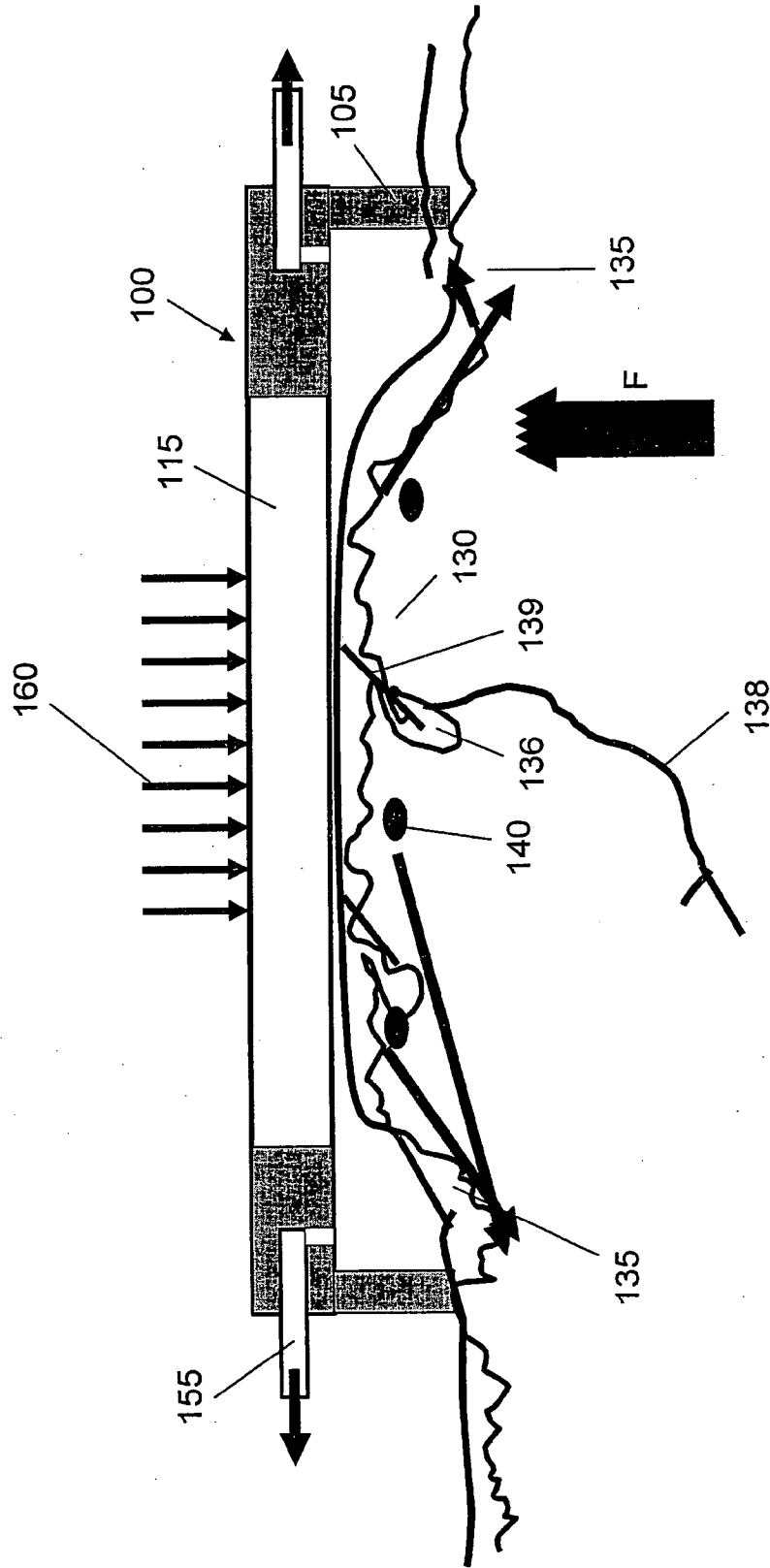


Fig. 22

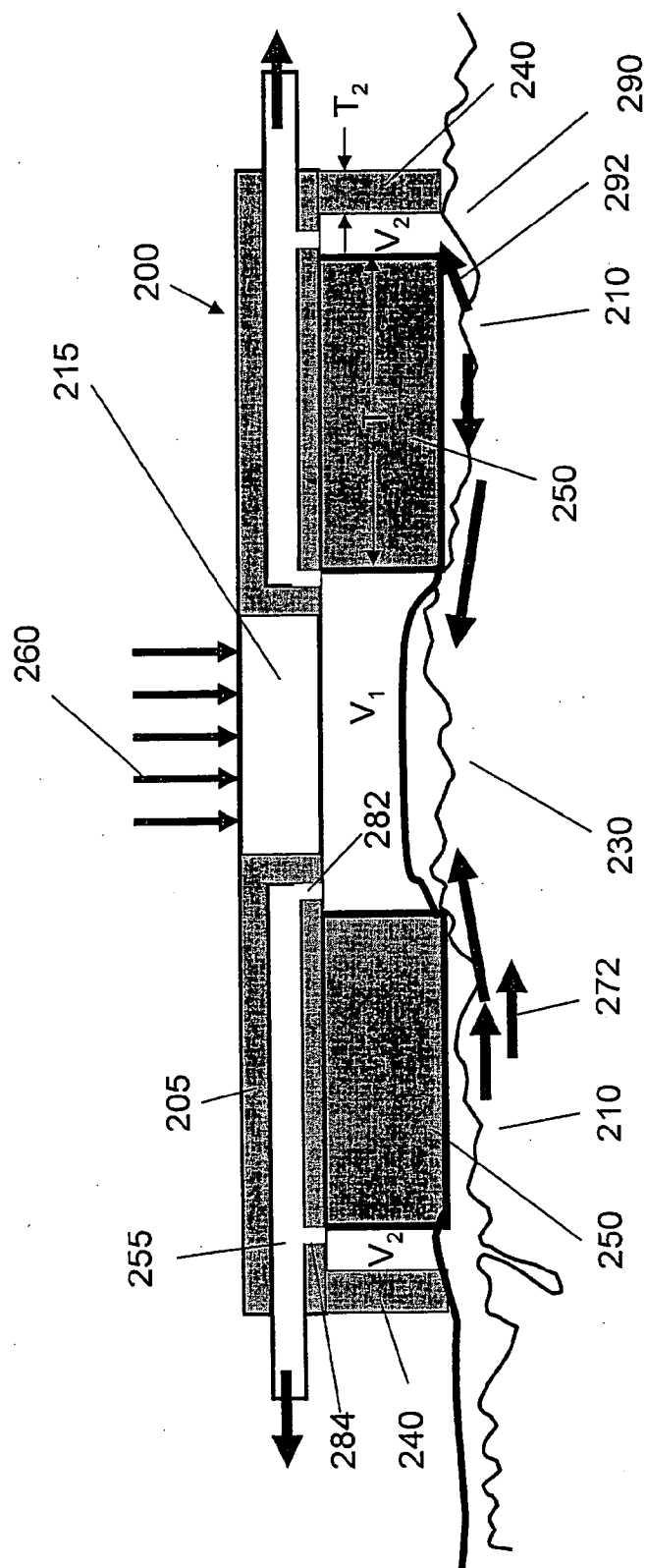


Fig. 23

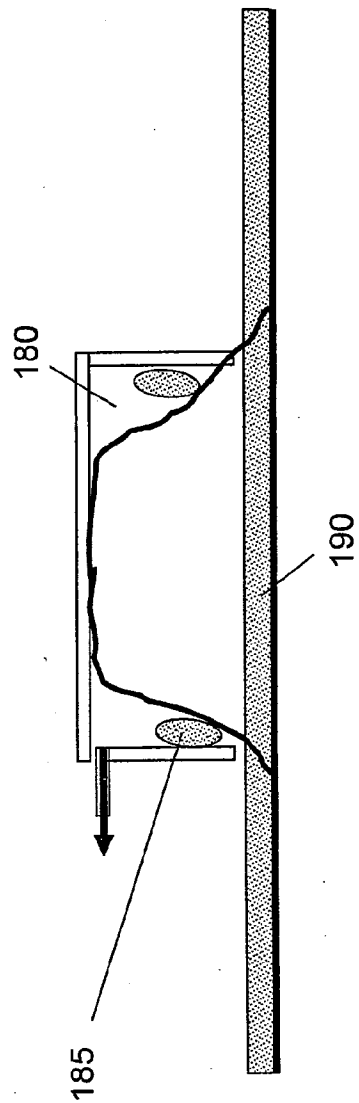


Fig. 24A

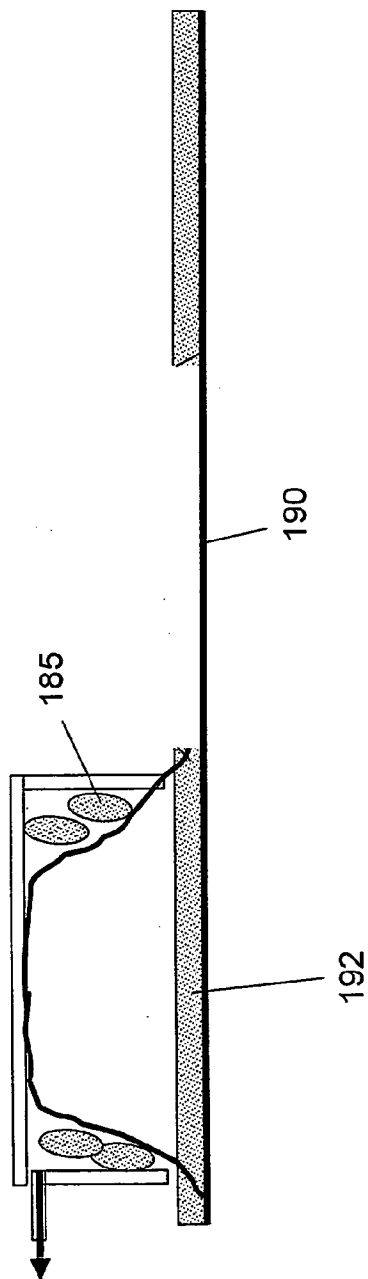


Fig. 24B



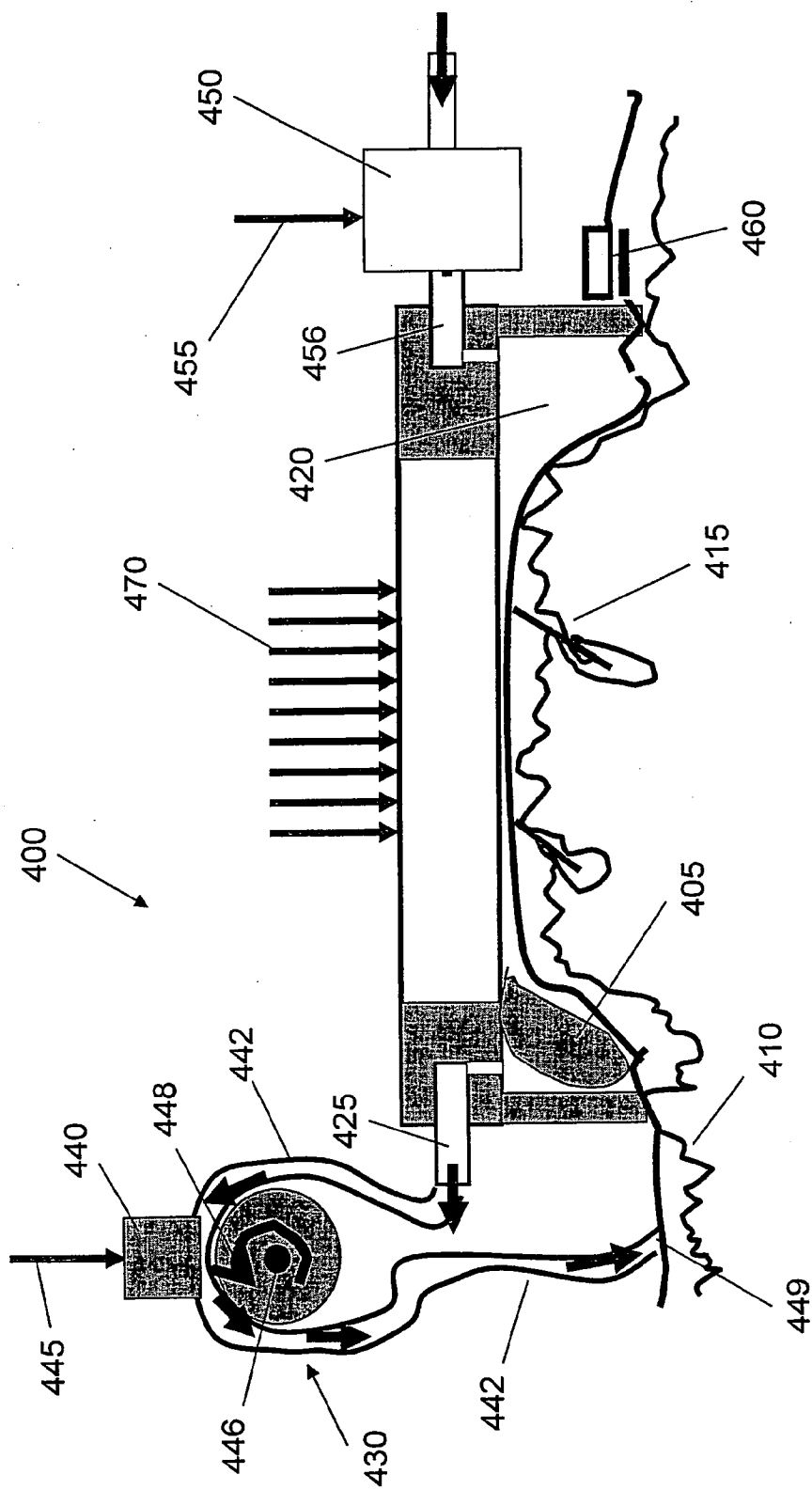
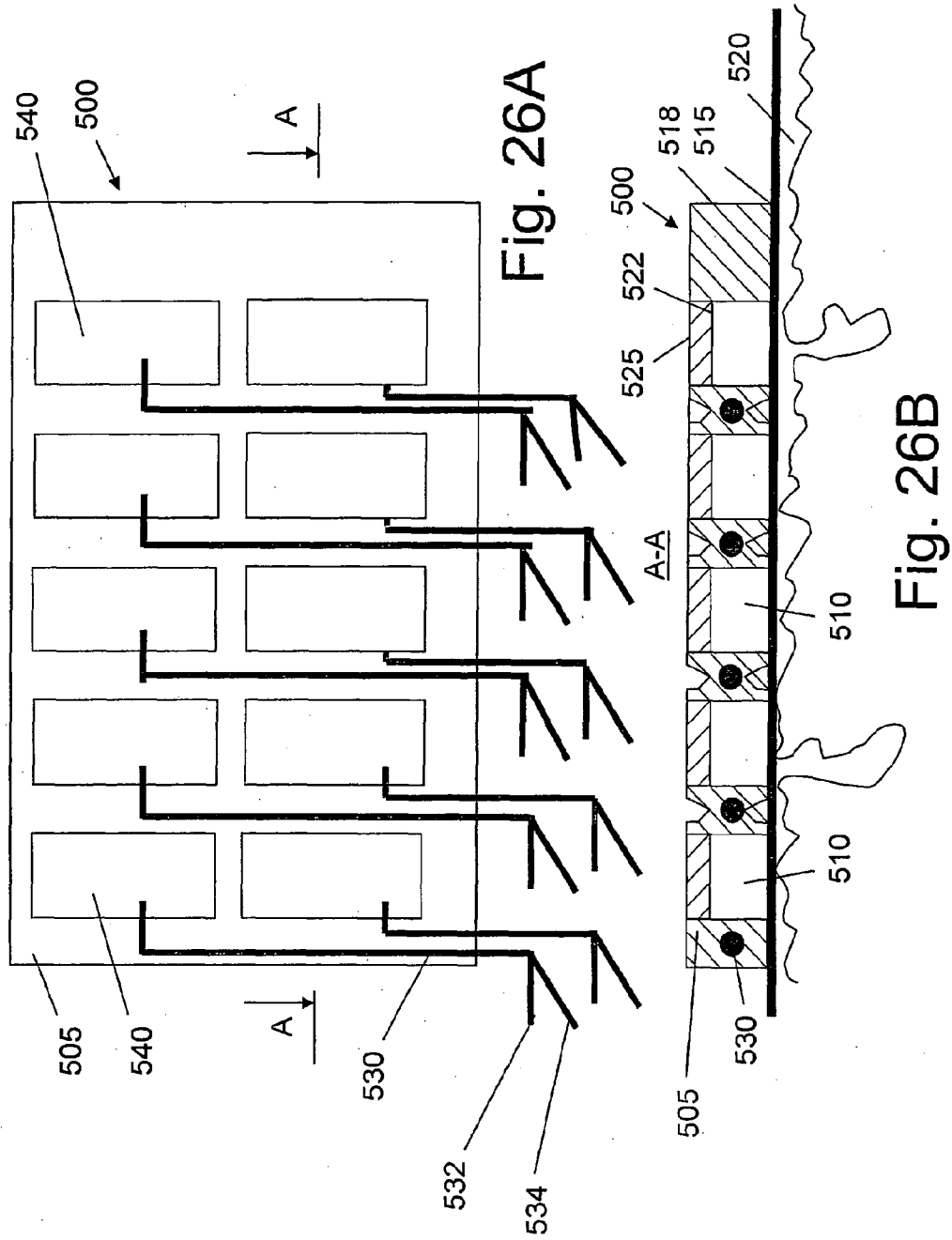
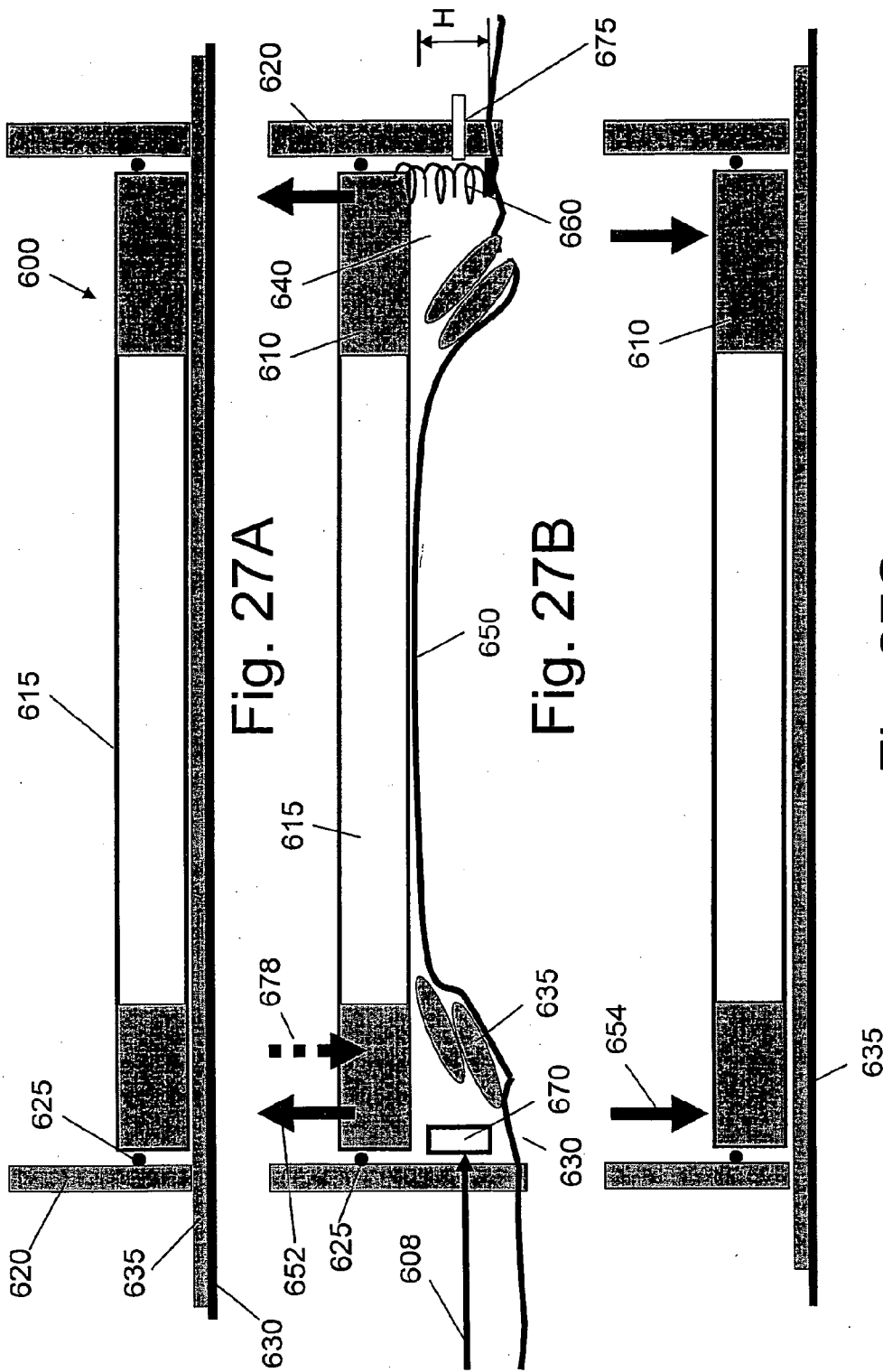


Fig. 25





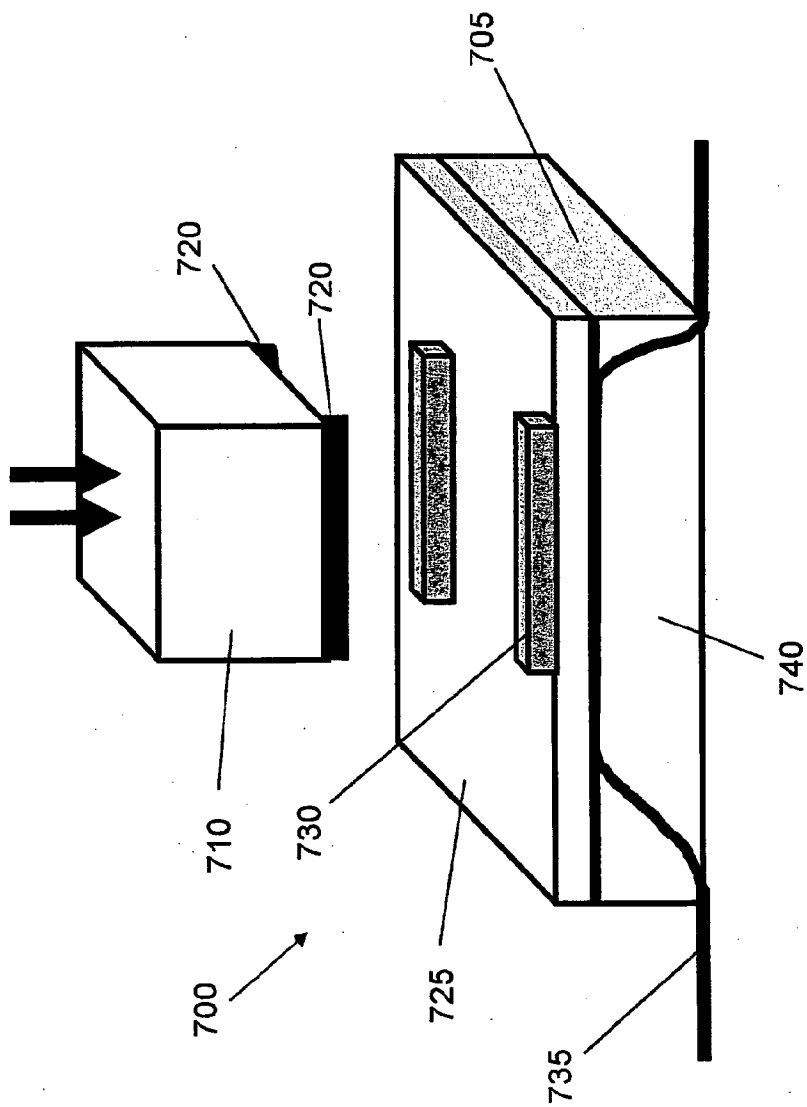


Fig. 28



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Application Number  
EP 05 00 7952

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The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 15 June 2005	Examiner Chopinaud, M
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... &amp; : member of the same patent family, corresponding document</p>			

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EP 05 00 7952

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**EP 1 839 705 A1**

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(30) Priority: **27.03.2006 ES 200600796**

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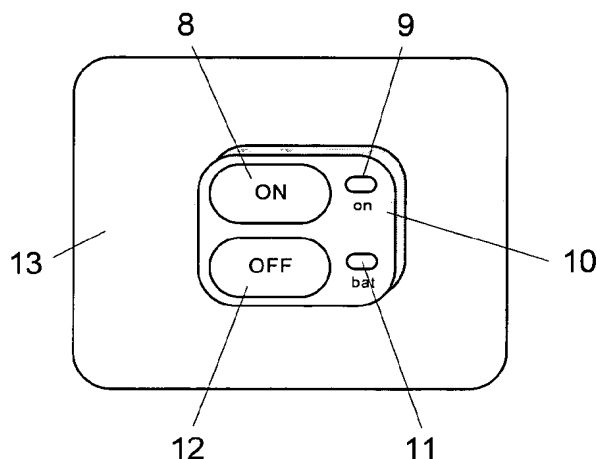
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(54) **Transcutaneous laser therapy patch**

(57) The present invention relates to a low-intensity laser therapy patch consisting of a laser emitter for the transcutaneous and instant application, and which is de-

signed with an output power of the laser diode that is fixed or variable, for selecting the laser energy density for the treatment of different medical pathologies.



**FIGURE 2**

**EP 1 839 705 A1**



**Description****FIELD OF THE ART**

- 5 **[0001]** The present invention relates to a low-intensity laser therapy apparatus for its transcutaneous and instant application in any part of the body for the treatment of different medical pathologies or aesthetic treatments.

**STATE OF THE ART**

- 10 **[0002]** Class IIIA, IIIB and IV low-intensity laser is applied therapeutically radiating both large body surfaces and point-based areas on small areas for the treatment of multiple diseases such as tendonitis, tendonosis, peripheral paralysis, muscle pains, epitrochleitis, epicondylitis, sprains, arthrosis of the base of the thumb, plantar heel pains, back pains, osteoporosis, contusions, herpes zoster, joint pains, muscle contractures, neuralgias, arthritis, sciatica, periarthritis, arthrosis, gonarthrosis, cervical arthrosis, edemas, fractures and injuries. These therapeutic applications are extended to different medical specialties: traumatology, rheumatology, dermatology, vascular, odontology and neurology (Jan Tuner and Lars Hode: Laser Therapy. Clinical practice and scientific background. Prima Books, Sweden, 2002)

- 15 **[0003]** The therapeutic effects of low-intensity laser are based on the biochemical, bioelectrical and bioenergetic effects caused by the photons in their interaction with biological structures. These effects are an increase of the production of adenosine triphosphate (ATP) and of proteins, an increase of cell proliferation and tropism, increase in microcirculation, changes in the permeability of the cell membrane, increase in endorphin and serotonin levels, increase of lymphocytes and increase of lymphatic flow.

- 20 **[0004]** The traditional technique of applying low-intensity laser therapy is carried out by means of equipment located in hospitals and clinics for a certain number of sessions and by means of short time periods. The large limitation existing in the clinical application of this technique consists of the existence of a time period from its clinical indication until its therapeutic application on the patient, and this technique not being available immediately or in the patient's home.

- 25 **[0005]** The laser energy penetrates more deeply in the skin contact technique; it is applied by means of sensors that the therapist applies manually and requires more treatment time.

- [0006]** The non-contact technique uses a higher density of laser power to compensate for the distance between the opening of the beam and the treatment area, effective treatment times are shorter and they usually automatically radiate the beam by scanning it over the tissue.

- 30 **[0007]** In both techniques, the action depth of the low-intensity laser therapy, combining the direct and indirect effects, can reach up to 3 cm and is in accordance with the wavelength, intensity and collimation of the beam and of the anatomical feature of the application surface.

- 35 **[0008]** The different parameters forming part of the correct selection of the dosage of low-intensity laser therapy are: the rated power of the laser (milliwatts, mW), laser power density (watts per square centimeter, W/cm<sup>2</sup>), energy (Joules, J), energy density (Joules per square centimeter, J/cm<sup>2</sup>), treatment surface area (square centimeter, cm<sup>2</sup>), distance from the laser emission point to the therapeutic target (centimeters, cm), radiation time, type of the emission: pulsating or continuous, working cycle (%), pulse repetition frequency (cycles per second or Hertz, Hz), pulse duration (nanoseconds or microseconds, ns or ms), laser wavelength (nanometer, nm) and beam divergence (degrees, °).

- 40 **[0009]** The dosage of the low-intensity laser energy is comparable to a pharmacological model in which a substance is supplied at a certain dose for the purpose of achieving a therapeutic effect.

- [0010]** The most widely used parameter for the laser therapy dosage is the energy density, which is quantified in Joules/cm<sup>2</sup> and uses the following formula for its calculation:

45

$$J/cm^2 = \frac{\text{Average power (W)} \times \text{Exposition time (s)}}{\text{Surface area (cm}^2\text{)}}$$

50

- 55 **[0011]** There is a laser energy dosage for the treatment of different pathologies according to the previously mentioned parameters based on the therapeutic experience of years of using this technique. For example, the following are the energy density dose for lower back pains (6 J/cm<sup>2</sup>), periarthritis (6 J/cm<sup>2</sup>), gonarthrosis (4 J/cm<sup>2</sup>), epicondylitis (3 J/cm<sup>2</sup>), sprain (4 J/cm<sup>2</sup>), carpal tunnel syndrome (4 J/cm<sup>2</sup>). The dosage based on energy density generally ranges from 1 J/cm<sup>2</sup>

to 99 J/cm<sup>2</sup>.

[0012] Laser therapy equipment today is carried out in solid state or by means of semiconductor laser diodes. High-intensity light emitting diodes (LED) have reduced this technology, which have allowed the use of radiation with a diagnostic target of the laser in small or point-based areas such as in Doppler laser equipment, laser oximetry or laser spectroscopy.

[0013] The permanent or transient application of different types of therapeutic patches is used in the treatment of different diseases, for example: patches with medicinal products (US 2004097864), (US 6143320), (US 5154182), (US 2004043062), (JP 2002121136), (HV 0002085); electrostimulation patches; iontophoresis patches (MXP A01007996), (US 2002183685), (KR 2002013249), (US 6424862); heat-generating patches (US 2004097864); magnetotherapy patches (US 6344021), (US 3943912), (US 4587956), (US 5312321), (US 5707333). However, there are no therapeutic low-intensity laser patches.

## EXPLANATION OF THE INVENTION

[0014] The present invention relates to a laser therapy patch for its transcutaneous application, applied instantly, having automatic operation and being used at home.

[0015] The laser therapy patch consists of a power supply or battery, a control circuit supervising functioning and activating the laser diode which generates a visible light or infrared laser beam.

[0016] The dose is administered instantly and automatically by means of the patient's activating an "on" button and the deactivation by an "off" button (although both functions can be carried out by a single "on/off" button according to the prior art and for the purpose of simplifying and reducing space).

[0017] The laser patch is placed transcutaneously and all the parameters forming the laser energy dosage are kept constant with the exception of the exposure time, which is variable, whereby a different energy density is generated for each disease.

[0018] With the laser patch, the laser energy dosage applied in each treatment according to its pathology is based on the fact that the parameters for calculating the energy density (J/cm<sup>2</sup>), mean power (W), energy (J) and the treatment surface area (cm<sup>2</sup>) remain steady, changing the exposure time according to the energy dose (J) indicated for each treatment.

[0019] Based on the foregoing, a different energy density is obtained for each clinical situation according to the following formula:

$$\text{Time} = \frac{\text{Dose per Surface}}{\text{Mean power}}$$

[0020] The mean power is calculated as follows:

$$\text{Mean power (Wm)} = \text{Wp} \times \text{Tp} \times \text{F}$$

[0021] Where Wm is the mean power (W), Wp is the peak power (W), Tp is the pulse duration (ns or ms) and F is the pulse frequency (Hz).

[0022] In the most simplified type, the considered power will be the maximum power of the laser diode given that a pulse working regimen is not applied, its functioning being continuous and therefore the mean power will be equal to the maximum power of the laser diode.

$$\text{Energy (J) x Surface (cm}^2\text{)}$$

$$\text{Time (s) = } \frac{\text{Energy (J) x Surface (cm}^2\text{)}}{\text{Mean power (W)}}$$

**[0023]** The advantages of this type of application of laser therapy are: ability to be reused by the patient for an undetermined number of sessions (the battery can be replaced), local therapeutic actions, non-invasive and painless technique, transcutaneous placement, immediate and instant application, non-pharmacological therapeutic agents, offering multiple pathologies for treatment, portable application (it is not necessary to go to a clinic or hospital to apply it), technique that is complementary or alternative to traditional therapy, very simple activation and automatic operation, low consumption and low cost. Since the laser is located in the part in contact with the skin and the upper part is made of an opaque material, it is not necessary to wear glasses for its therapeutic use.

#### DESCRIPTION OF THE DRAWINGS

**[0024]**

Figure 1 shows a circuit block diagram of the transcutaneous laser therapy patch. It shows the battery or power supply (1), on-off position switches (2 and 3), control circuit (7), operating indicator (4), low battery indicator (5) and laser emitter (6).

Figure 2 shows an upper view of the laser therapy patch, showing the "on" button (8) for the activation of the laser once positioned in the place to treat, the "off" button (12) for deactivating the laser, the operating indicator (9) notifying that the laser is on, the low battery indicator (11) notifying that the battery needs to be replaced and a battery cover (10) for accessing the battery compartment to replace it.

Figure 3 shows a lower view of the laser therapy patch, showing the laser output opening (14) and adhesive (15).

Figure 4 shows a cross-section view of the laser therapy patch, showing the "on/off" buttons (16), operating and low battery indicators (18), the battery (17), adhesive (22), a diode or laser diode array or laser emitter (21) including the optics for distributing the beam, an opening (20) where the laser diode beam exits and a control circuit (19) for controlling and exciting the laser diode.

Figure 5 shows a replaceable adhesive system for holding the laser therapy patch to the surface of the body with its central part (23) and peripheral part (24).

#### EMBODIMENT

**[0025]** The laser therapy patch (Figure 1) consists of a battery or power supply (1 and 18), a control circuit (2 and 19), diode or diode array or laser emitter (6 and 21) and a changeable adhesive system (13 and 15).

**[0026]** The optical system is located in the central lower part (Figure 3) and is formed by an opening (14 and 20) which may have a lens and a laser diode or diode array.

**[0027]** The laser diode or diode array generates a visible light or infrared laser beam. The output power of the laser diode or diode array will depend of the area to be treated and will therefore be treated according to its class. The laser diode or diode array will be excited from the control circuit.

**[0028]** The control circuit continuously supervises the correct operation of each of the components to assure the output power of the laser diode and for prevent overheating or malfunction. The energy for feeding the control circuit and therefore the laser diode or diode array is powered by the battery although a feed input can be provided from an external feeder or power supply.

**[0029]** The lower part of the patch (Figure 3) contains an opening (14) in its central part from where the laser radiation is emitted. The dimensions of said opening will be suitable for the surface area to be treated.

**[0030]** The "on" and "off" buttons (16) (or just one "on/off" button for simplifying and reducing space) are located in the upper part of the laser patch (Figure 4) to control the start of treatment and for the interruption thereof, and operating and low battery indicators (17).

**[0031]** An adhesive system (Figure 5) allows maintaining the patch on the surface of the body and consists of a central dome part (23) covering the patch of a transparent and flexible material and an adhesive peripheral part (24) coated with a coating paper.

**[0032]** The present invention is additionally illustrated by means of the following example of the treatment parameters,

which do not aim to be limiting of its scope.

Example: Treatment of Epicondylitis

[0033] Therapeutic target: To administer an energy density of 2 J/cm<sup>2</sup>.

[0034] According to formula:

$$\text{Time} = \frac{2 \text{ J/cm}^2 \times 2.25 \text{ cm}^2}{5 \times 10^{-3} \text{ W}} = 900 \text{ s} = 15 \text{ min}$$

Energy density (2 J/cm<sup>2</sup>)  
Power of the diode (5 mW)  
Treatment surface (2.25 cm<sup>2</sup>)  
Radiation time = 15 minutes

**INDUSTRIAL APPLICATION**

[0035] The invention can be applied in the electromedicine, physiotherapy, rehabilitation, aesthetics, odontology and veterinary fields.

**Claims**

1. A transcutaneous laser therapy patch **characterized in that** it consists of a power supply or battery (1) activating an operating control circuit (7 and 19) exciting a semiconductor diode or diode array (6 and 21) or another laser emitter for its instant transcutaneous application with automatic functioning by means of an independent adhesive system (13, 15, 23 and 24).
2. A transcutaneous laser therapy patch according to claim 1, **characterized in that** the laser used is a class IIIA or IIIB low-intensity laser and can be formed by one or several laser diodes or diode array, or other laser emitters (6 and 21) acting simultaneously or sequentially and with continuous or pulsating emission in any of its combinations.
3. A transcutaneous laser therapy patch, according to claims 1 and 2, **characterized in that** it contains a control circuit powered by a battery or power supply (1 and 18), exciting the laser emitter and supervising and controlling the parameters of the laser energy to be applied in different therapeutic treatments. The control circuit supervises the power and prevents the overheating or malfunction of the system.
4. A transcutaneous laser therapy patch, according to claims 1 and 3, **characterized in that** the control system consists of an activation and deactivation button for starting and ending the treatment (2, 3, 4, 8, 9, 12 and 16) as well as the operating state of the battery or power supply (5 and 11).
5. A transcutaneous laser therapy patch according to the previous claims, **characterized in that** its external configuration can vary in design, shape and size, as well as the configuration of the laser equipment and the skin adherence system according to the surface areas to be treated.
6. A transcutaneous laser therapy patch according to the previous claims, **characterized in that** it has an industrial application in the electromedicine, physiotherapy, rehabilitation, aesthetic, odontology and veterinary fields, with advantages of use by the patient immediately and instantly, non-invasive techniques and easy to use and operate.

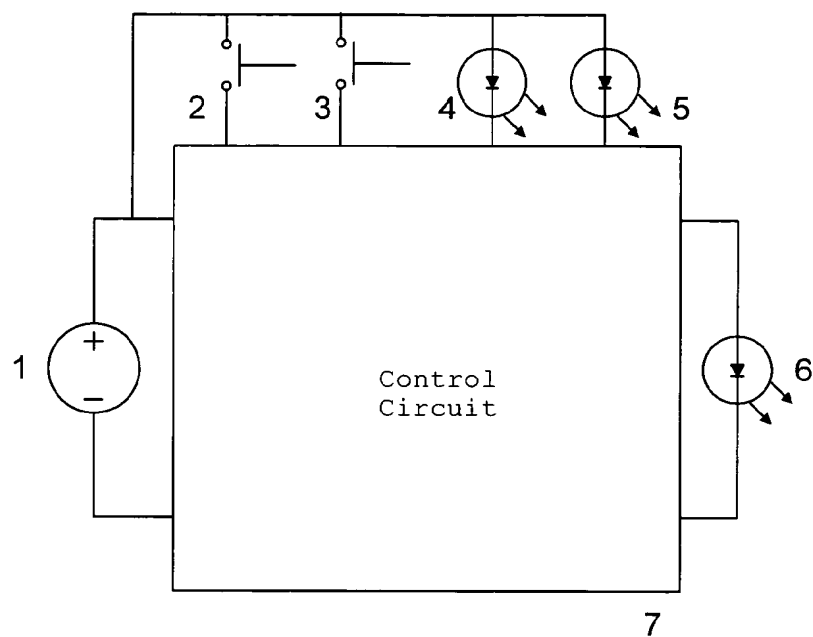


FIGURE 1

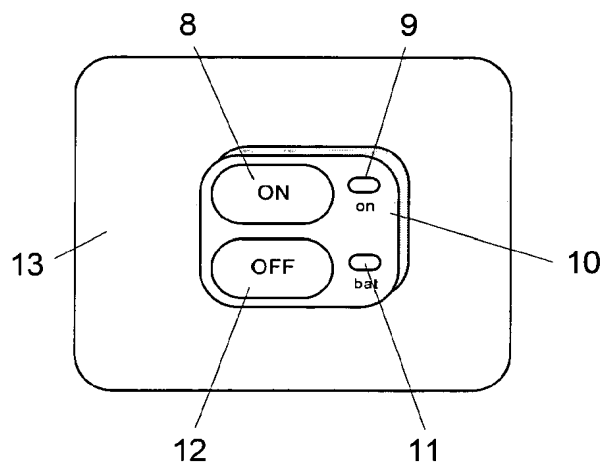
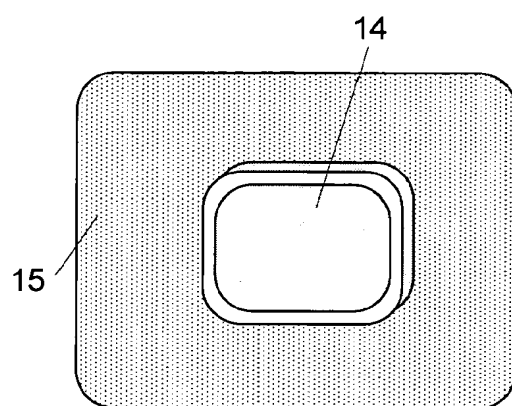
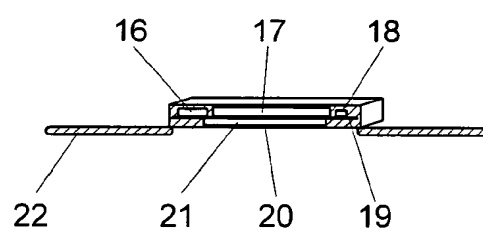


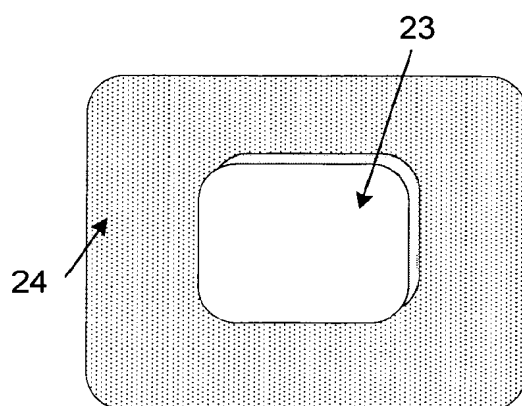
FIGURE 2



**FIGURE 3**



**FIGURE 4**



**FIGURE 5**



European Patent  
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Application Number  
EP 07 38 0080

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Place of search The Hague		Date of completion of the search 24 July 2007	Examiner Petter, Erwin
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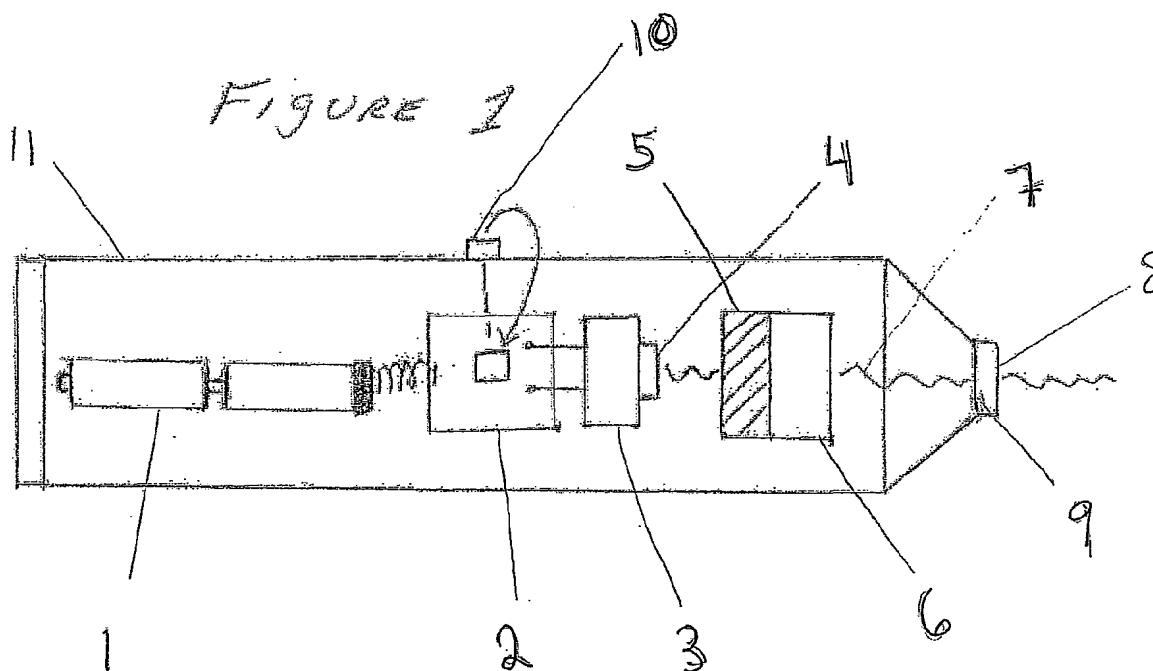
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(54) **Device and method for treating musculo-skeletal injury and pain by application of laser light therapy**

(57) A laser therapy device and method of treatment for treating musculo-skeletal pain. The device and treat-

ment employ a composite laser beam comprised of multiple frequencies of laser energy.



**EP 1 854 505 A2**

## Description

### CROSS-REFERENCE TO RELATED APPLICATION:

**[0001]** This application for utility patent claims priority from Provisional Patent Application 60/746,668, filed on May 8, 2006, entitled: Device and Method for Treating Musculo-Skeletal Injury and Pain by Application of Laser Light Therapy.

### FIELD OF INVENTION:

**[0002]** The present invention lies in the field of medical devices. In particular, it relates to the treatment by means of laser light of musculo-skeletal pain and wounds.

### BACKGROUND OF THE INVENTION:

**[0003]** Laser Light Therapy is well known in the treatment of a wide variety of medical conditions whereby the laser emits light at certain specific bio-effective frequencies. In various applications, it is used to treat musculo-skeletal pain caused by injury or chronic and acute conditions. A non-exhaustive list of the conditions treated by Laser Light Therapy includes whiplash, arthritis, migraine, lower back pain, tendonitis, carpal tunnel syndrome, tennis elbow, golfer's elbow, strains, sprains, knee, neuropathy, ankle and foot pain, TMJ, and soft tissue injuries. The therapy is also useful in treating and promoting wound healing.

**[0004]** Depending on the nature and extent of the treated injury, the effects of Laser Light Therapy may be either curative or palliative. Where soft tissue injury is involved, such as in the case of sprains or strains, the device appears to promote direct healing of the injured tissue. If the injury is structural as in the case of a torn ligament or bone fracture, the device provides palliative relief and may be used in conjunction with other treatments.

**[0005]** Laser light consists of discrete coherent light of a wavelength from a narrow spectrum of electromagnetic radiation ("EMR"). In general it is amplified EMR that is monochromatic, collimated, polarized and concentrated in a relatively defined location or spot. Low Level Lasers are considered to be lasers varying in power intensity from 1 mW to 500 mW and are commonly used in therapy. The properties of laser light in general are such that it penetrates the surface of the skin without, or when desired with only limited, associated heating. Laser light is well known to possess and direct bio-stimulating energy to the cells of the body which, in turn, facilitates and enhances the body's own healing and pain regulating mechanisms.

**[0006]** Laser Light Therapy appears to be an effective treatment because of its ability to enhance the maintenance or restoration of biological systems to proper conditions of homeostasis and its ability to initiate or amplify the body's own regenerative systems. Injury or other chronic conditions may have a deleterious affect on cel-

lular systems and thereby compromise the cell's ability to regulate its functioning or to effect repairs where tissue has been damaged. Where cell membranes have been damaged, laser light therapy enhances receptor-mediated movement across the cell membrane. Thus it has a positive effect on the cell's ability to maintain or restore proper function, repair of the cell's enzyme systems and re-establish the proper balance of proteins, ions or carbohydrates to allow the cell to function normally. Often, the addition of energy to the cell system can restore proper function and balance as the cell is re-stabilized and homeostasis is restored.

**[0007]** In laser therapy, photonic energy is emitted from a laser source. The energy, in the form of photons, is absorbed by photo acceptor sites on the cell membrane. This in turn triggers the cell's biochemical pathways which initiate the transmission of a variety of signals initiating, inhibiting or accelerating a variety of biological processes. These processes include inflammation reactions, cell growth or pain blocking. Furthermore, photonic energy is known to promote and optimize antiinflammatory and immuno-stimulative effects.

**[0008]** In general, the significant biological effects of laser light are known to include cell growth stimulation and cell regeneration which positively affect connective tissue, tendons, bone, muscles and nerves. Laser light therapy promotes revascularization of damaged or injured tissue leading to positive therapeutic effect. Further, laser light therapy is known to improve microcirculation in injured or damaged tissue thereby relieving, for example, edemas, and facilitating the healing of in treating torn or damaged muscle tissue. It further acts to inhibit inflammation of afflicted areas by inhibiting the ability of leukocytes to trigger increasing inflammation responses. It is also known to reduce fibrous tissue formed in response to injury.

**[0009]** At the cellular level, Laser Light Therapy is also well-known to increase the levels of adenosine triphosphate (ATP) produced by the mitochondria of the cell. One effect of laser light is to promote and stimulate cytochromes, including porphyrin, to produce singlet oxygen during the creation of ATP. ATP, in turn, plays a critical role in transporting energy within the body's cells and tissue and thus greater levels of ATP act to stimulate higher levels of cellular activity. Increased ATP production promotes increased levels of various growth factors and higher levels of protein synthesis, which are key for cellular repair and functioning.

**[0010]** Under the stimulation of laser light energy, greater degrees of cell proliferation have been observed. Other beneficial effects include increased levels of endorphin release leading to pain relief, both acute and chronic. Increased lymphocytic activity leading to a stronger immune response is also observed. Another well known beneficial effect of laser therapy is the promotion of revascularization of the blood and lymph vessels in response to therapy. This is particularly useful in treating edema and contusions related to injury or trau-

ma.

**[0011]** Presently, lasers of particular wavelengths are known in the prior art. None, however, disclose the art of a composite beam comprised of laser energy emitted at wavelengths of 532 nm, 805 nm and 1064 nm which this device in its preferred embodiment does. An example of this is Patent 5,464,436 which uses laser light within the range of 800-870 nm, more preferentially 830 nm, to treat a variety of musculo-skeletal injuries and conditions. Other therapeutic devices used for treating injuries and musculo-skeletal pain include laser emitting light at frequencies in the range of 635 nm at approximately 5 mW of power. While relatively powerful lasers emitting light at wavelengths of 532 nm are used by surgeons in the removal of tattoos and by dentists for bleaching or whitening teeth, the use of such frequencies is little known in the treatment of musculo-skeletal pain and injury. An example of one patent that does employ a similar frequency is U.S. Patent # 6,582,454 to Yayama. While Yayama does use a beam emitted at a frequency of 530 nm in connection with other beams, none of the other beams include frequencies of the infrared spectrum. Laser light at that frequency is known to be readily absorbed by hemoglobin. Therefore it is used in ablating blood vessels and treating other cosmetic skin conditions caused by blood vessels such as port wine stains. It is further known to readily penetrate the skin.

**[0012]** Furthermore, in lasers that are used to treat musculo-skeletal pain, the emitted therapeutic light is typically of one wavelength only, typically ranging from 635 nm to 980 nm. While multi-diode lasers may be used, the diodes usually emit identical frequencies of EMR and thus merely increase the energy deposited without varying the spectrum of the treating light source. Where multiple-diode lasers have been employed that emit different wavelengths, such as in Patent 4,669,839, only one wavelength has been selected for its therapeutic quality and effect. A second wavelength is typically used as a guide beam to assist in directing the therapeutic beam. When multiple frequencies are used to treat musculo skeletal conditions as in the '454 Patent, the frequencies have not included similar combinations of frequencies as disclosed herein and in fact differ in their characteristics. The instant device for example includes infrared wavelengths which allow greater penetration of the tissue than visible wavelengths as in the '454 Patent. Furthermore, in the instant invention, the laser beams do not intersect and then diverge as in Yayama but rather are emitted as a composite beam and this too facilitates the deeper penetration of the target tissue than Yayama. Not only does the composite beam penetrate more deeply than Yayama without diverging, each component beam of the composite beam simultaneously strikes the same target tissue and from the same angle. Furthermore, in at least certain embodiments of this device, at least two (2) composite beams form an octave, here the 532 nm beam and the 1064 nm beam or at least approximate an octave.

#### Summary of the Invention:

**[0013]** The present invention uses multiple beams of different frequencies to provide improved beneficial therapeutic and palliative effects of laser therapy. Preferably, at least one of the multiple frequencies should fall within the 532 nm range. Heretofore the therapeutic effects on musculo-skeletal conditions of lower frequency lasers in the 532 nm range has gone unappreciated. Indeed there is currently no therapeutic device or treatment practiced employing the use of a laser beam emitting EMR at that frequency. Thus one aspect of the present invention is the use of EMR at the heretofore unused 532 nm frequency in the treatment of musculo-skeletal injury and pain.

**[0014]** Further, the treatment of such conditions by a laser beam composed not of a single therapeutic frequency but from energy of different, simultaneously emitted, therapeutic wavelengths is not known or practiced. The present invention thus provides a therapeutic method and device for treating pain and tissue damage employing both features. The present invention generates a multifrequency beam reaching transcutaneously into afflicted tissue without causing significant heating and employing energy of a heretofore unused therapeutic, lower frequency in combination with energy of higher frequencies. Based upon observed treatments using the present invention, the use of a laser beam emitting a variety of frequencies as in the present invention appears to have a synergistic effects on the treatment of musculo-skeletal pain and injury.

**[0015]** It should be appreciated, furthermore, that use of this device is not limited to the treatment of humans. Indeed, the disclosed device should also prove useful in treating any mammals.

**[0016]** The present invention in one embodiment relies upon a lasing source that generates a laser beam having a frequency of 532 nm at a power of up to 65 mW. Additionally, the beam, according to one embodiment of the invention, transmits additional EMR at wavelengths of 808 nm and 1064 nm and at a combined power of no more than 435 mW but closer to 200 mW. Further the beam produced is relatively dispersed in order to minimize any associated thermal effects on the areas of the body treated. The device may be specially manufactured or adapted from preexisting commercially available devices.

**[0017]** It should be readily appreciated by those skilled in the art that a composite laser beam having the characteristics set forth herein may be generated by other means. For example, individual laser devices or diodes could be used to generate isolated beams which through the use of beam splitters could then be merged to form a composite laser beam. Additionally a variety of mirrors or other optics could be employed to merge multiple beams so that same could be emitted as a composite beam through a single aperture.

**[0018]** The specific frequencies are not considered

limitations of the device and surrounding frequencies in combination may prove equally effective. Thus, a device according to the present invention may include EMR from higher or lower frequencies around the ranges disclosed herein. EMR from the yellow bandwidth, ranging up to 594 nm, which is also known to be readily absorbed by hemoglobin, may also be included. So, too, may intermediate frequencies in the range of 808nm to 980 nm be encompassed in the device, whether emitted from a single diode or multiple diode laser. Further, frequencies in the range of 1064 nm to 1300nm may similarly be encompassed in the device.

[0019] Additionally, the power output of the laser is not considered to be a limitation, and more powerful or less powerful lasers may also be employed according to the instant invention. For example, lasers incorporating 1-5 Watt pump diodes and generating energy beams of similar frequencies may also yield similar beneficial results.

[0020] The selection of a laser beam composed of energy of lower, heretofore unused wavelengths in combination with higher frequencies has been observed to yield highly positive results in the treatment of various musculo-skeletal conditions, including but not limited to those identified above, when therapeutically applied.

[0021] In the first aspect of the method for treatment according to the invention, the health care provider diagnoses the afflicted area of the patient to determine specific treatment points associated with the condition for which relief is sought. The treatment may be applied to a wide variety of musculo-skeletal conditions and structures of the body. The present invention may beneficially treat conditions including, but not limited to, inflammation, necrosis/gangrene, hematomas, edema, contusions, strains, sprains, avulsion, ruptures, arthritis and other chronic and acute pain. In addition the treatment may be used to promote wound healing. In the treatment, Laser Light Therapy targets a array of various tissue structures of the body that may be associated with the condition. These include skin, subcutaneous tissue, mucous membranes, muscle, tendon, the vascular system, the lymph system, joints of the skeletal system, the nervous system, as well as the periosteum.

[0022] Diagnosis may employ various examination techniques including: (1) palpation of the afflicted region to determine areas of sensitivity and tenderness; (2) visual observation including regions of swelling, redness or similar; (3) viewing of x-rays, MRIs or other imaging depictions; or (4) recourse to known or determined acupuncture points, and the tracing of the peripheral nerve supply of the affected tissue to its spinal source level. The second step involves treating the patient by applying the barrel of the laser device onto the afflicted-area in an appropriate pattern and for an appropriate duration thereby applying a proper dosage of laser light. Many times, irradiating the damaged tissue will elicit a pain response from the patient, confirming the existence of pathology. Where wounds are treated, the therapy is somewhat modified in that the barrel of the laser is not directly ap-

plied to the afflicted area. The wound area is irradiated as well as the healthy tissue on the periphery. During this phase, the above outlined treatment may be repeated a number of times in response to the results observed by the health care provider and feedback from the patient. The treatment may further incorporate the application of light therapy along the peripheral nerves and concluding at the spinal segment supplying the afflicted areas. Depending on the severity of the condition and the results of initial treatment, follow up visits may be appropriate over a period of days and weeks. More specific treatment protocols that represent variations on this general treatment are described below.

#### Brief Description of the Drawings

[0023] Fig. 1 shows a schematic of the device according to one aspect of the present invention

[0024] Fig. 2 shows the device in operation.

#### Detailed Description of the Preferred Embodiments

[0025] Fig. 1 shows the device according to one aspect of the present invention. In the device as shown, a power source, 1, is connected to a 500 mw driver board, 2. While standard AAA batteries are shown, it should be readily apparent to one skilled in the art that other power sources may be employed. A standard plug-in electrical connection, for example, could also be used. The power source is used to power the driver board, 2, here a 500mW driver board. The driver board, 2, in turn powers an 808 nm pump laser diode, 3. The diode, 3, emits a beam through a microlens, 4. The resultant beam is then emitted through an NDYV04 crystal, 5, and thereafter through a KTP crystal, 6. The resultant composite laser beam is emitted through a collimating lens, 8, and then through a single aperture, 9. The resultant laser beam is comprised of laser energy emitted at approximately 532 nm, approximately 808 nm and approximately 1064 nm.

[0026] The device also incorporates a shut-off switch, 10, that allows the user to regulate the duration of the application of the composite beam and also to prevent the device from overheating and otherwise burning out the laser diode. The danger of overheating is controlled by the relatively short durations of the application. In other embodiments, the laser device may incorporate heat sinks, cooling fans or other mechanisms for regulating the thermal output of the device and controlling associated problems. The device as shown may be housed in a casing, 11, of suitable size and shape for being held in the hand of an operator.

[0027] In another embodiment of the invention the laser beam may be emitted as a pulse beam. Thus, the beam includes pulsed laser energy emitted at least at approximately 532 nm. Said composite beam may further included a beam emitted at approximately 808 nm and a beam emitted at approximately 1064 nm.

[0028] The device may also include associated meters

or gauges showing information on the status of the device including its power level, the levels of its emitted light or similar information on the functioning of the specific device. The device may further be sold as part of a kit wherein the kit includes treatment protocols, maintenance protocols or other written materials that may focusing on the use of the device.

**[0029]** A composite beam of laser energy emitting energy at the frequencies claimed herein may also be prepared by modifying a commercially available laser such as a GaAlAs 808 nm Diode Pumped Solid State (DPSS) laser powered by a 500 mW driver. The device is fitted with suitable crystals to generate laser light of the appropriate, 532 nm, 808 nm and 1064 nm frequencies however commercially available laser devices do not emit such beams. The crystals may include a KTP (Potassium Titanium Oxide) crystal and an ND: YVO4 (Yttrium Vanadate) crystals. DPSS lasers are equipped to filter energy from the 808 nm and 1064 nanometer frequencies and thus do not emit a composite beam. The device is modified by removing those filters and thereby emits electromagnetic radiation at those wavelengths in addition to the green laser light at 532 nm, something the device was incapable of doing as originally configured. The output of the laser shown in this embodiment consists of EMR as follows: up to 65 mW of 532 nm green laser light and as much as 435 mW of 808 nm and 1064 nm EMR. Further, the laser beam in this particular embodiment is emitted as a continuous wave rather than a pulsed beam. In other embodiments, however, pulsed beams may be generated and used.

**[0030]** Additionally, the focusing lens of the device is removed in order to generate a more diffuse beam which minimizes any thermal effect caused by the higher wavelength beams and the energy output of the device. The device shown is equipped with a shut-off switch which allows the health care provider to control the duration of the beam emission and ameliorate the risks of overheating the device. The device may be hand held when housed in a casing of suitable shape and size.

**[0031]** FIG. 2 shows a device according to the instant invention being applied to a condition under treatment, here a knee, 20. The beam, 21, which is comprised of energy at wavelengths of 532 nm, 808 nm and 1064 nm, is applied directly over the afflicted tissue at an angle of approximately 90°. Application at this angle will maximize penetration by the photonic energy of the dermal layers to varying depths according to the wavelength of the emitted energy. In treating musculo-skeletal pain, the tip of the laser device, 22, may be held directly against the treatment point for the afflicted area and applied in a linear, back and forth motion at a rate of approximately 1 inch every 3 seconds not to exceed a treatment duration of 30 seconds. The device is then turned off for at least approximately 5 seconds and the process is repeated for up to 10 times, depending on the extent and degree of injury and responsive feedback from the patient. Thus the dosage per treatment will usually range up to 150

Joules. Dosages vary per condition and severity, however, as prescribed by the health care provider. Further, actual dosage on the target tissue is variable with not all of the laser energy reaching the target tissue. Thus in many applications, the dosage at the surface of the skin significantly exceeds that on the target tissue.

**[0032]** As the therapy is administered, the laser deposits energy in the form of photons within the afflicted cells. While not wishing to attribute the beneficial results achieved by the invention to any specific theory or modality, it appears that the application of EMR in accordance with the invention stimulates the nerves and increases circulation to the area under treatment. In turn, this increases blood flow and oxygen to the area under treatment and thus additional endorphins are released and pain enzymes are blocked.

**[0033]** Depending on the condition being treated, various effects appear to contribute to the efficacy of the treatment. For treating musculo-skeletal conditions such as sprains or strains, and other inflammations, the therapy may be applied as described above. By compressing the tissue as pressure is applied to the epidermis of the patient, the underlying, afflicted tissue structures may be brought into a closer proximity to the energy beam. Thus the different frequencies may reach the target tissues and energize the associated cells.

**[0034]** In treating musculo-skeletal pain, the treatment protocol concludes with the application of therapeutic light along the peripheral nerves and into the spinal segment where those nerves terminate and connect to the Central Nervous System. Laser Light Therapy is believed to enhance receptor activity on cell membranes associated with the production of endorphins. Accordingly, bio-stimulation by laser light enhances the production of endorphins with a resulting decrease in pain associated with the underlying condition. In addition, laser light is known to decrease production of bradykinin, which is one of the main causes of pain. Further, laser light therapy suppresses the excitation of the unmyelinated C-fibers, thereby alleviating pain associated with musculo-skeletal injury.

**[0035]** In treating wounds, the above treatment may be somewhat modified since direct contact with the wound may cause pain or discomfort or otherwise negatively effect the healing of the wound. In treating wounds, the laser is held immediately above the afflicted region and healthy tissue around the periphery. Application of the Laser Light Therapy has a positive effect on the production of granulation tissue during the proliferative phase of repairs. It also stimulates increased collagen synthesis as well as the activation and migration of macrophages and fibroblasts to the area of injury. Further Laser Light Therapy encourages the proliferation of mast cells as well as increases in endothelial cells and keratinocytes. In addition, Laser Light Therapy may increase the transport of ions, including possibly calcium ions, across the cell membrane and increase the cell's ability to transmit signals bringing about cell repair. Further-

more, the above effects all enhance the body's regenerative system to bring about wound healing.

**[0036]** Several more specific treatment protocols are variations on the above generalized therapy regimen. For treatment of persistent headaches, for example, the health care provider treats peripheral triggerpoints, including mid trapezius and suboccipital muscles with the application of laser light therapy and then treats the area of perceived head pain both with the laser barrel head contacting the skin.

**[0037]** The device may also be used to treat traumatized gum tissue, e.g. from a tooth extraction. In those cases, the health care provider should splay the beam over the area of involvement for at least 90 seconds. There should be no skin contact with the end of the barrel. Skin contact can then be made to trace the branches of the trigeminal nerve.

**[0038]** For oral mucosal trauma, the same protocol is an effective treatment.

**[0039]** Where treating joint pain in a patient, the health care provider applies EMR through directly contacting the laser head to the surface of the area to be treated irradiating the joint space, tendon attachments and the attendant muscle belly(s) with EMR. There should be a further continuation of nerve tracing to the spinal segment supplying the joint structures.

**[0040]** In treating acute cervical spinal injury with spasm and stiffness, for example, caused by auto accident, lifting injuries, or similar, the specific protocol is as follows. With the patient in a sitting position and the health care provider standing behind patient, the laser head of the device is applied with pressure to the skin over the spinous processes, interspinous ligaments, posterior cervical muscles, sternocleidomastoid muscle and mid trapezius (bilaterally). The treatment commences with a slow sweeping motion over the above-described areas. During treatment, the patient may complain of stinging pain over area of greatest inflammation. This will occur even with no skin contact. The patient is instructed to turn head to tolerance in order to stretch the involved tissues as laser light treatment is applied.

**[0041]** For a lumbar injury, the patient stands while supporting weight with hands on a table or wall in front of the patient. The health care provider applies the laser head to the patient's skin and moves the beam over the lumbar muscles, and medially to the interspinous ligaments, and medially to the spinous processes, all performed in a caudal to cephalic and then reversed motion. The beam is also run along the posterior thighs and calves. During treatment, the patient is instructed to bend forward to tolerance in order to stretch involved tissues. If possible, in the treatment of all spinal conditions, treatment should be performed while the spine is loaded and not while the patient is recumbent.

**[0042]** In the case of patients suffering from radiculopathies caused by spinal nerve root dysfunction, precipitated by biomechanical pressure or altered local physiology, the treatment may consist of irradiating the

entire neural pathway of the afflicted nerve, starting at the peripheral innervation and ending at the spinal segment that the nerve root exits from.

**[0043]** Furthermore, the treatment protocols may include variable dosages depending on the condition treated. Thus treatment dosages at the target tissue may include the following:

#### TREATMENT FOR RECENT INJURIES

Shoulder: 40-50 joules

Knee: 20 joules

Ankle: 40 joules

#### CONDITIONS

Strains: 5-10 joules per point. 35-50 joules total treatment

Osteoarthritis

- Interarticular: 4-8 joules per joint

- Extra articular: 2-4 joules per point

#### TOTAL DOSAGE

Ankle/Foot: 20-30 joules

Knee: 20-40 joules

Spine: 4-16 joules per vertebral motor unit, with additional treatment directed to the supporting musculature

These ranges are rough guides for treating some target tissue in response to some conditions and injury, but they are not intended as limitations. Indeed, higher dosages have been observed to yield positive and, at times, improved results.

**[0044]** The embodiment of the device disclosed in FIG. 1 has been tested on various patients suffering from a variety of musculo-skeletal conditions. For example, a 45-year-old female with a severe sprain on the left lateral ankle was treated pursuant to the therapy protocol outlined above and with the device described in FIG. 1. Unable to walk due to pain and severe swelling, laser light therapy was applied to the afflicted ankle over a total treatment period of five minutes. The result was a 75% reduction in swelling and an immediate ability to walk on the affected ankle with minimal pain. The effects of the treatment were not diminished by time and the patient had a full recovery in less time than would be expected due to the nature of this injury.

**[0045]** A 30-year-old female suffering from a complete tear of the anterior cruciate ligament was also treated. The patient had difficulty walking due to the injury. After applying the treatment outlined above with the same device, the patient reported markedly less pain on ambulation, even though the device did not repair the severed ligament.

**[0046]** Further, a 60-year-old male with a severe intercostal muscle sprain was treated 2 weeks post injury duration. The patient, employed as an industrial airconditioning mechanic was unable to perform job duties due to inability to fully extend left arm and twist trunk due to

severe pain in the lateral rib cage. The patient was treated as set forth above with the same device over the affected area. Upon treatment, the patient was virtually asymptomatic and exhibited a full range of motion of the trunk and left arm. Follow-up research three days later revealed that the patient remained virtually asymptomatic.

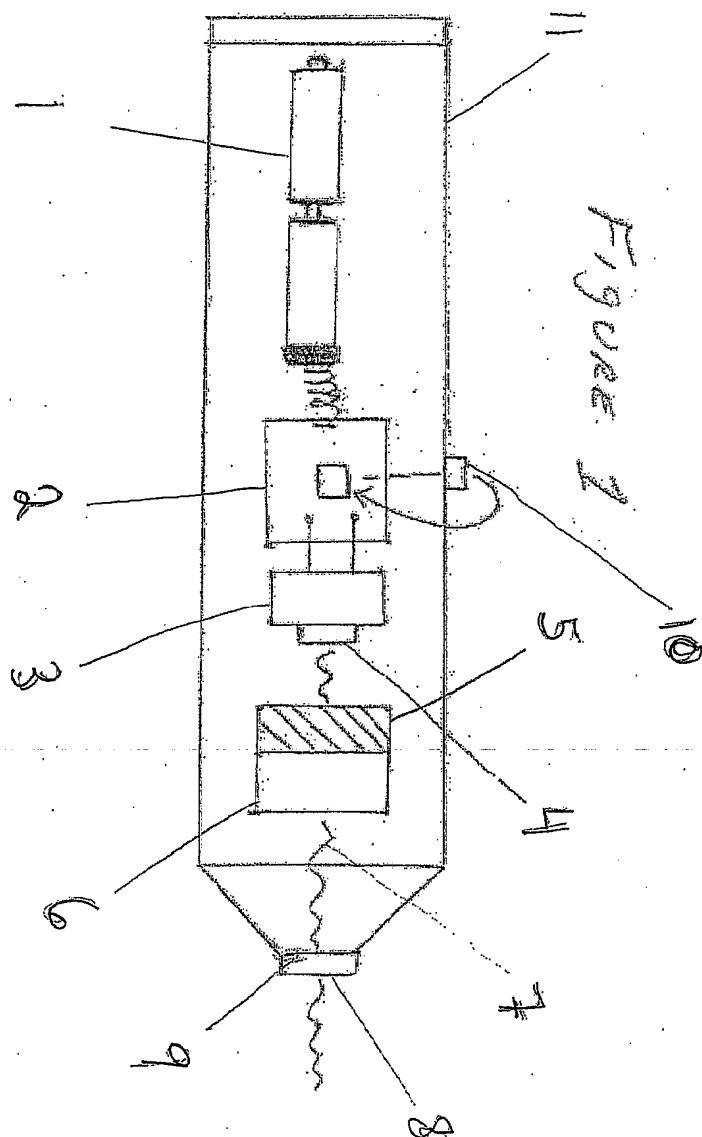
**[0047]** Further, a nonagenarian patient who had suffered a fall injuring her lower back, left knee and left foot. In addition, she suffered in part from a persistent numbness on the sole and lateral aspect of her left foot. The neuropathy was treated by application of laser light from the device along the injured foot, knee, the sciatic nerve distribution network and at the lumbar spine. As a result of the therapy, the patient reported that normal sensation in the previously numb foot had been restored.

**[0048]** Another patient suffering a bilateral rotator cuff tear was also treated with the device as outlined above. Prior to treatment, the patient exhibited an extremely limited range of motion with the injured shoulder. Post treatment, the patient was able to fully extend the injured shoulder. Although the pain associated with the torn rotator cuff did return, the palliative effect was pronounced and treatment was considered successful.

## Claims

1. A laser therapy device for generating a composite laser beam comprised of a plurality of laser beams at least one of the plurality of beams being emitted at a wavelength of approximately 532 nm, a second such beam being emitted at a wavelength of approximately 808 nm and third such beam being emitted at a wavelength of approximately 1064 nm.
2. A laser therapy device comprising a power source, a driver board, an 808 nm pump laser diode, a microlens, a NDYV04 lasing crystal, a KTP lasing crystal, a collimating lens, and a single aperture, said device when in operation emitting a composite laser beam comprised of at least a first beam emitted at a frequency of approximately 532 nm, a second beam emitted at a frequency of approximately 808 nm and a third beam emitted at a frequency of approximately 1064 nm, said composite beam being emitted through a single aperture.
3. The laser therapy device in claim 2 wherein said device is housed in a hand held wand.
4. The laser therapy device of Claim 1 in which said device has a total power output of no more than 500 mW.
5. The laser therapy device of Claim 2 in which said device has a total power output of no more than 500 mW.
6. The laser therapy device of Claim 1 in which said device has a total power output of no more than 2W.
7. The laser therapy device of Claim 2 in which said device has a total power output of no more than 2W.
8. A method of providing laser therapy to a patient comprising the steps of;
  - diagnosing the patient's area of musculo-skeletal pain;
  - applying a laser therapy device at or near the surface of the patient's skin proximate to said area of musculo-skeletal pain;
  - causing said device to emit a composite laser beam comprised of beams emitted at a plurality of frequencies including at least one beam emitted at a frequency of approximately 532 nm, a second of said beams emitted at a frequency of approximately 808 nm, and a third of said beams emitted at a frequency of approximately 1064 nm; and
  - manipulating said device in a pattern and for a duration over said area of musculo-skeletal pain.
9. A method for generating a composite laser beam for use in administering laser light therapy comprising the steps of:
  - removing the infrared filter and the focusing lens of a 500 mW GaAlAs laser fitted with an ND: YV04 crystal and a KTP crystal; connecting said laser to a power source; causing said laser to emit a composite laser beam; the composite laser beam comprising component laser beams emitted at a frequency of approximately 532 nm, approximately 808 nm, and approximately 1064 nm; and emitting said composite beam over a relatively broad area.
10. A kit for treating musculo-skeletal pain comprising:
  - a laser therapy device capable of emitting a composite laser beam;
  - said composite laser beam being comprised of a plurality of laser beams;
  - said plurality including a laser beam emitted at a frequency of approximately 532 nm;
  - a second laser beam emitted at a frequency of approximately 808nm;
  - a third laser beam emitted at a frequency of approximately 1064 nm;
  - wherein said kit further includes written materials which may address information relating to the maintenance and use of said laser therapy device, various technical features of said device or treatment protocols, either general in nature or specific to various conditions.





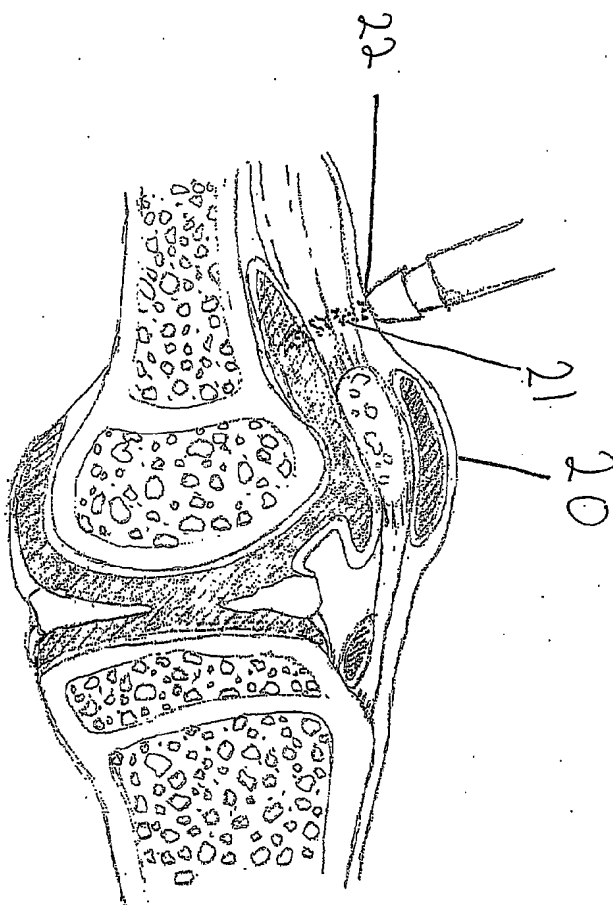


Fig. 2

**REFERENCES CITED IN THE DESCRIPTION**

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**Patent documents cited in the description**

- WO 6074668 A [0001]

# DEMANDE DE BREVET D'INVENTION

1<sup>re</sup> PUBLICATION

- ②2 Date de dépôt ..... 12 mai 1972, à 9 h 5 mn.  
④1 Date de la mise à la disposition du  
public de la demande..... B.O.P.I. — «Listes» n. 15 du 12-4-1974.
- ⑤1 Classification internationale (Int. Cl.) A 61 b 6/00//A 61 n 5/00.
- ⑦1 Déposant : BUSSER Francis Paul, résidant en France.
- ⑦3 Titulaire : *Idem* ⑦1
- ⑦4 Mandataire :
- ⑤4 Dispositif de refroidissement cutané pour la photothérapie et le photodiagnostic aux hauts  
et très hauts niveaux lumineux.
- ⑦2 Invention de : Francis Paul Busser.
- ③3 ③2 ③1 Priorité conventionnelle :

L'invention intéresse en médecine humaine, la photothérapie et le photodiagnostic, utilisations thérapeutiques et diagnostiques de la lumière.

5 Dans ces domaines, la tendance actuelle est d'utiliser des niveaux lumineux toujours plus élevés. Cela est particulièrement vrai en transillumination par exemple; une des branches essentielles du photodiagnostic, où résolution et contraste obtenus avec des organes volumineux tels le sein, sont d'autant meilleurs que le diamètre de la zone illuminée est petit.

10 Or pour une bonne perception des faibles contrastes, il est indispensable que la luminance de l'image diaphanoscopique corresponde pour l'opérateur à des conditions de vision photopique. Pour réduire le diamètre de la zone cutanée illuminée à quelques millimètres, cela conduit à appliquer des niveaux lumineux de  
15 l'ordre de 10 à 100 millions de lux, même avec un spectre réduit à la bande du visible la moins absorbée par les tissus. Toute l'énergie lumineuse non transmise ni diffusée est dégradée en chaleur. L'échauffement des tissus est d'autant plus grand que la profondeur est faible et suit une loi exponentielle complexe dont l'expression mathématique est d'ailleurs encore imparfaitement  
20 définie. Avec les techniques actuelles des niveaux supérieurs à 1 ou 2 millions de lux ne sont pas tolérés sur la peau plus de quelques secondes, voire fractions de secondes. Cette limitation restreint l'efficacité de la photothérapie et oblige à augmenter le diamètre éclairé en photodiagnostic, d'où perte de résolution.

25 La concentration essentiellement superficielle de cet effet thermique permet d'envisager un refroidissement forcé de la zone cutanée éclairée, d'autant qu'une absorption importante est due à l'irrigation capillaire sur laquelle le froid exerce une action vasoconstrictive favorable à la transmission lumineuse. Mais le  
30 gain en dissipation admissible est faible, à moins d'utiliser un fluide de refroidissement à très basse température, ce qui n'est pas dépourvu de risque et en tous cas désagréable pour le patient.

35 L'invention proposée évite ces inconvénients et vise à permettre l'application locale sur la peau, durant des périodes prolongées, de niveaux lumineux plusieurs fois supérieurs à ceux normalement tolérés. Elle fait de la sorte réaliser un progrès considérable tant à la photothérapie qu'au photodiagnostic.

Elle tire parti d'un certain nombre de réactions opto-physiologiques des tissus cutanés:

- a) en présence d'un refroidissement cutané, le niveau lumineux indéfiniment toléré sur la peau est beaucoup plus élevé si ce  
5 refroidissement s'exerce sur une zone de diamètre plusieurs fois supérieur à celui de la plage illuminée, l'effet étant d'autant plus marqué que cette plage est petite.
- b) une compression par une surface rigide transparente de la zone illuminée provoque une occultation partielle de la vasculari-  
10 sation superficielle conduisant à un gain de transparence complémentaire à celui de la vasoconstriction due au refroidissement. L'effet est à peine atténué si cette compression n'est localisé qu'à la limite extérieure de la zone refroidie, dans la mesure où  
15 le diamètre de cette zone refroidie reste de l'ordre de 20 à 30 mm.
- c) un massage de la plage illuminée et de sa périphérie favorise l'entraînement par la circulation sanguine de la chaleur libérée dans les zones dermiques profondes et hypodermiques adjacentes.

L'invention réside en une série d'aménagements originaux d'un  
20 éclaireur de photothérapie ou photodiagnostic classique et de système non critique. Elle s'applique aussi bien dans le domaine du visible que dans les domaines adjacents du proche infra-rouge ou ultra-violet. Ces dispositions sont les suivantes.

Les dimensions de la fenêtre de sortie de la lumière de cet  
25 éclaireur sont choisies plusieurs fois supérieures à celles de la plage éclairée (Planche unique, figures 1 et 2, repères 1).

Le bord de cette fenêtre est taillé en saillie de plusieurs millimètres par rapport au corps de l'éclaireur, et constitué par  
une matière dure permettant la compression des tissus (métal par  
30 exemple) et formant localisateur (Fig. 1 et 2, repères 2)

Une membrane, transparente dans le domaine spectral utilisé, ferme le localisateur (Fig. 1 et 2, repères 3). Cette membrane a pour rôle de séparer les tissus cutanés du fluide de refroidissement et de participer à leur compression tout en leur transmettant  
35 le cas échéant un massage vibratoire. En conséquence elle est réalisée en un matériau mince et bon conducteur de la chaleur. De plus, tout en restant élastique elle doit présenter une certaine fermeté pour pouvoir contribuer à la compression des tissus. Celle-ci est obtenue indifféremment par sa rigidité propre ou par une  
40 tension adéquate. De nombreuses matières depuis les verres jusqu'

aux polyesters, polycarbonates et autres résines macromoléculaires peuvent convenir à la constitution de cette membrane.

Un revêtement dichroïde sélectif formant filtre interférentiel peut être appliqué sur la membrane pour sélectionner la bande spectrale pénétrant dans les tissus.

La face de cette membrane interne à l'éclaireur est soumise à un refroidissement énergétique par circulation d'un fluide liquide ou gazeux de température plus basse que celle de la peau et qui évacue à travers la membrane la chaleur libérée dans les tissus cutanés superficiels (fig. 1 et 2, repère 4)

L'association de ces 4 premiers moyens, fenêtre de dimension excédant celles de la plage illuminée et formant localisateur compresseur des tissus, membrane échangeuse thermique et refroidissement force des tissus superficiels à travers cette membrane, permet avec un refroidissement par de l'eau à 25° C seulement de supporter sur la peau des intensités lumineuses de l'ordre de 10 millions de lux, soit déjà quelque 5 à 10 fois supérieures à la limite tolérable sans ces dispositifs. Avec des températures du fluide de refroidissement plus basses un gain plus élevé encore peut être réalisé.

Le fluide ayant refroidi les tissus à travers la membrane est avantageusement recupéré pour le refroidissement des autres organes de l'éclaireur. Les fig. 1 et 2, repères 5 donnent deux exemples d'une telle récupération. De plus dans le cas d'un liquide, l'addition d'un colorant adéquat lui permet de jouer accessoirement le rôle de filtre sélecteur de la bande spectrale admise dans les tissus.

Dans le cas particulier d'un fluide gazeux, l'épiderme lui-même peut remplir l'office de membrane échangeuse (membrane virtuelle), surtout s'il s'agit d'un gaz peu onéreux et pouvant sans inconvénients s'échapper à l'atmosphère (air comprimé par exemple). Dans ce cas également, le refroidissement de ce fluide pourra être obtenu par détente immédiatement au voisinage de la membrane ou de l'épiderme de ce gaz amené sous haute pression.

Les tissus cutanés présentent une résistance thermique relativement élevée, de sorte que l'efficacité du refroidissement superficiel décroît plus vite avec la profondeur que l'échauffement dû à la dégradation en chaleur de l'énergie lumineuse absorbée. Même en abaissant la température du fluide de refroidissement au voisinage de 0° C, limite qu'il est dangereux de dépasser

ser de beaucoup, si l'intensité lumineuse continue à croître, il vient un moment où dans les zones dermiques profondes et hypodermiques adjacentes, l'élévation de température dépasse le seuil tolérable.

- 5 Or dans ces zones où le froid n'exerce plus d'action vasoconstrictive et où la compression elle-même en raison de l'élasticité des tissus n'a plus guère d'effet, un massage vigoureux et rapide favorise la circulation sanguine qui évacue une fraction importante des calories libérées par l'absorption de la lumière.
- 10 Il permet donc d'élever encore les niveaux lumineux et d'approcher les 100 millions de lux. En photothérapie cela assure des traitements plus efficaces, en photodiagnostic cela autorise des diamètres illuminés plus petits, d'où meilleure résolution sans que la luminance image soit abaissée.

- 15 Exercé sur la périphérie du localisateur, ce massage n'a qu'une efficacité réduite. Celle-ci n'est optimale que si c'est la zone illuminée et son entourage immédiat, c'est à dire en pratique l'intérieur du localisateur qui sont soumis au massage.

- Manuellement, cet effet peut être obtenu par des mouvements
- 20 axiaux du localisateur. Mais la faible cadence réalisable n'assure qu'une efficacité modeste. L'impression mécanique ou électromécanique de mouvements vibratoires axiaux à l'ensemble du localisateur apporte une amélioration importante de l'efficacité, mais présente l'inconvénient de transmettre des vibrations de
- 25 grande amplitude à la main de l'opérateur ce qui à la longue risque d'être traumatisant. Cet inconvénient disparaît si les vibrations sont imprimées à la seule membrane et c'est pourquoi elle doit présenter une certaine élasticité.

- Plutôt que de recourir à un ébranlement mécanique de la
- 30 membrane, l'invention tire parti de l'observation suivante: le débit du fluide de refroidissement exerce une pression, c'est à dire une force, sur la membrane. En faisant varier ce débit, cette force varie également. Opposée à l'élasticité de la membrane, elle se traduit donc par des déformations variables de la membra-
- 35 ne. Par conséquent en modulant périodiquement le débit du fluide de refroidissement, la membrane est le siège de vibrations périodiques synchrones qui assurent le massage cutané recherché. En faisant varier la fréquence il est possible selon les tissus traités ou explorés d'obtenir un régime d'ondes stationnaires ou
- 40 progressives, voire de résonance, selon le but recherché.



La modulation du débit de fluide refroidisseur peut être obtenue par exemple par variation de la section de ses conduits d'arrivée ou d'évacuation.

La membrane en se bombant tantôt vers l'intérieur, tantôt vers l'extérieur du localisateur, sous l'influence de la modulation, constitue avec le fluide de refroidissement un dioptré tantôt positif, tantôt négatif. L'effet est d'autant plus prononcé que l'indice de réfraction du fluide est plus élevé. Il est sans inconvénient en photothérapie. En Photodiagnostic ses répercussions sur contraste et résolution sont imperceptibles, ces paramètres variant peu pour des variations modérées de l'angle de vergence du faisceau lumineux. Pour éviter par contre que contraste et résolution ne soient dégradés par des variations du diamètre de la plage illuminée liées aux déplacements de la membrane dans un faisceau lumineux cône, il est prévu que pour le photodiagnostic, l'optique de l'éclaireur forme l'image de la source lumineuse dans le plan de la membrane au repos (fig. 1, faisceau divergent) ou à l'infini (fig. 2, faisceau parallèle). De cette manière la membrane ne se déplace que dans une zone cylindrique ou quasi cylindrique du faisceau lumineux.

Les systèmes optiques schématisés en fig. 1 et 2 sont extérieurs à l'invention et donnés simplement à titre d'exemple. Toutes autres combinaisons optiques conduisant aux mêmes résultats sont utilisables; en particulier les dispositifs à émission stimulée dits "lasers" pourront présenter un vif intérêt le jour où ils seront réalisables à des puissances élevées sous un faible encombrement.

Aux niveaux moyens de l'ordre de 10 millions de lux, il peut être renoncé au vibromassage décrit plus haut. La caractéristique de souplesse de la fenêtre membrane échangeuse thermique est alors superflue et il peut y être renoncé. La membrane dans ce cas particulier pourrait sans inconvénient être constituée d'une matière rigide, pourvu qu'elle possède les autres qualités requises à savoir transparence dans le domaine spectral utile et bonne conductivité thermique.

Les très hauts niveaux lumineux autorisés par l'invention ouvrent de nouveaux horizons aussi bien en photothérapie qu'en photodiagnostic. En photothérapie en particulier, des travaux encore en cours semblent démontrer une action favorable sur certaines mycoses ainsi que sur quelques types de tumeurs des téguments,

alors que des niveaux de l'ordre du millions de lux généralement bien tolérés sans refroidissement cutané, auraient une influence plutôt défavorable sur les mêmes affections.

En photodiagnostic, et plus particulièrement en diaphanoscopie par transillumination, les très hauts niveaux lumineux autorisés par l'invention font faire un progrès considérable à ces disciplines en permettant de réduire de 10 à 100 fois la surface de la plage illuminée tout en conservant la même luminance de l'image diaphanoscopique. Il en résulte un important gain en résolution, c'est à dire que des structures opaques de plus petite dimension peuvent être décelées à un niveau donné d'un organe d'une épaisseur donnée. Au prix d'une réduction un peu moindre de la surface illuminée, c'est la luminance de l'image diaphanoscopique qui réalise un gain en luminance, facilitant l'introduction de la diaphanoscopie dans les méthodes diagnostiques de routine.

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REVENDECATIONS

- 1) la présente invention se rapporte à un perfectionnement des éclairateurs de photothérapie et de photodiagnostic classiques par l'adjonction d'un dispositif de refroidissement cutané permettant de supporter sur la peau des niveaux lumineux très élevés. Elle revendique la protection de ses caractéristiques techniques principales, à savoir:
- a) dimensions de la fenêtre de l'éclairateur débordant largement celles de la plage illuminée
  - 10 b) rebord en saillie de plusieurs millimètres, réalisé en matière dure, limitant la périphérie de la fenêtre de l'éclairateur et formant localisateur.
  - c) membrane mince, transparente dans le domaine spectral utile, bonne conductrice de la chaleur, ferme avec éventuellement une
  - 15 certaine souplesse ou élasticité, obturant le localisateur et permettant avec lui la compression des tissus
  - d) refroidissement de la face de la membrane intérieure à l'éclairateur par circulation d'un fluide de température inférieure à 37°C.
  - 2) l'invention revendique d'autre part la protection de ses caractéristiques secondaires optionnelles qui dans divers cas particuliers valorisent ses caractéristiques principales, soit:
  - e) possibilité de récupérer le fluide ayant servi au refroidissement de la membrane et à travers elle les tissus cutanés, pour assurer celui des autres organes de l'éclairateur
  - 25 f) possibilité d'adjoindre un colorant au fluide refroidisseur dans le cas d'un liquide, pour lui faire jouer le rôle d'un filtre optique sélecteur de bande
  - g) possibilité de déposer une couche dichroïde formant filtre interférentiel sélecteur de bande sur la membrane
  - 30 h) possibilité de faire jouer à l'épiderme lui-même le rôle de membrane échangeuse dans le cas d'un fluide de refroidissement gazeux pouvant sans inconvénient s'échapper à l'atmosphère
  - i) possibilité avec un refroidissement par fluide gazeux d'en obtenir le refroidissement par détente à proximité immédiate de
  - 35 la membrane
  - 3) l'invention revendique en outre la possibilité qu'elle offre de reculer plus loin encore les limites de la tolérance cutanée aux forts niveaux lumineux en associant un vibro-massage au simple refroidissement cutané, et ce par les moyens suivants:

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- j) attribution d'une certaine élasticité à la membrane
- k) transmission d'un vibromassage aux tissus par déformations périodiques de la membrane.
- l) obtention de ces déformations par modulation du débit de fluide de refroidisseur.
- m) réglage optique du faisceau lumineux de manière à pallier les inconvénients que pourraient avoir les déformations et déplacements de la membrane, ce réglage consistant soit en une focalisation de l'image de la source lumineuse dans le plan de la membrane au repos, soit en la réalisation d'un faisceau lumineux parallèle de diamètre adéquat.
- 4) l'invention revendique également protection des applications nouvelles qu'autorisent les hauts niveaux lumineux qu'elle rend applicables, soit en photothérapie le traitement de diverses dermatoses ou tumeurs cutanées, en photodiagnostic, la diaphanoscopie par transillumination à haute résolution d'organes épais tel le sein, par application de niveaux lumineux très élevés, entre 2 et 100 millions de lux, avec des diamètres éclairés réduits de l'ordre de quelques centimètres, jusqu'au voisinage du millimètre pour les niveaux les plus élevés.

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Figure 1

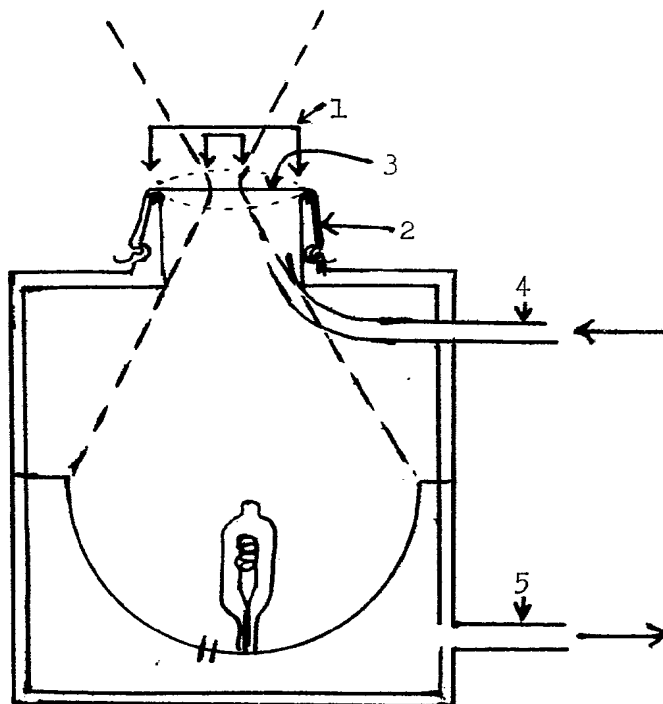
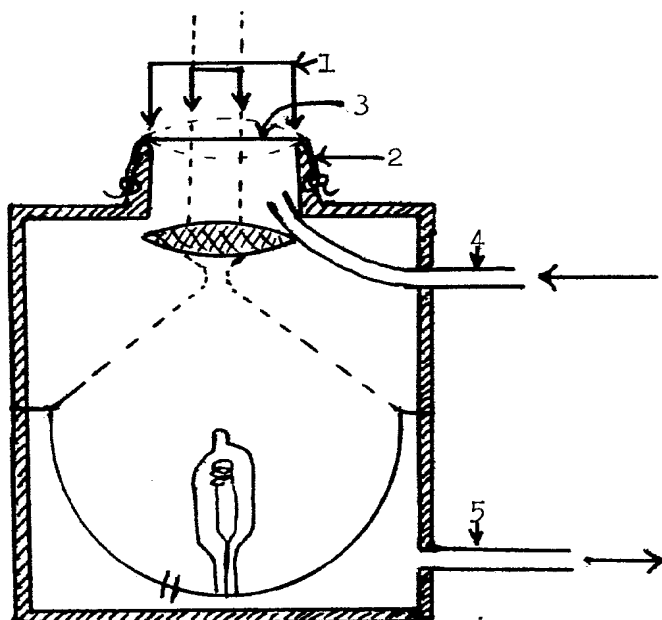








Figure 2

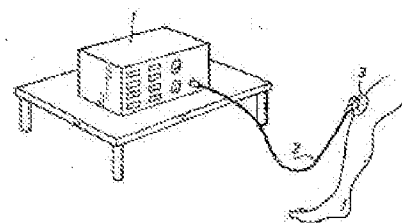


**External laser therapy apparatus comprising one or more laser diodes in suckers****Publication number:** FR2591902 (A1)**Publication date:** 1987-06-26**Inventor(s):****Applicant(s):** COLLIN YVON [FR]**Classification:****- international:** **A61B18/22; A61N5/06; A61B17/30; A61B18/20; A61N5/06;**  
A61B17/30; (IPC1-7): A61N5/06**- European:** A61B18/22; A61N5/06C2**Application number:** FR19850019208 19851223**Priority number(s):** FR19850019208 19851223**Also published as:** FR2591902 (B1)**Cited documents:** DE3134953 (A1) FR2527437 (A1) DE2404802 (A1) FR2492666 (A1) DE2742058 (A1)

more &gt;&gt;

**Abstract of FR 2591902 (A1)**

The subject of the invention is a laser therapy apparatus comprising one or more suckers each fitted with one or more laser diodes. An apparatus according to the invention comprises, on the one hand, one or more suckers 3 which are applied in contact with the skin of a patient. Each sucker contains a printed circuit carrying one or more laser diodes and, furthermore, a capacitor and an electronic switch with a chip associated with each diode. The apparatus comprises a casing 1 which contains part of the electronic circuits which control the charging of the capacitors and which send pulse trains onto the chip of the electronic switch. The casing 1 is connected to the suckers by a lead in which the electrical conductors pass, and a small flexible tube which connects the suckers to a suction apparatus. One application is the treatment of rheumatism of the joints.

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⑫

## DEMANDE DE BREVET D'INVENTION

A1

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⑫③ Priorité :

⑫④ Date de la mise à disposition du public de la  
demande : BOPI « Brevets » n° 26 du 26 juin 1987.

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⑦① Demandeur(s) : Société à responsabilité limitée dite :  
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⑦② Inventeur(s) : Yvon Collin.

⑦③ Titulaire(s) : COLLIN Yvon. — FR.

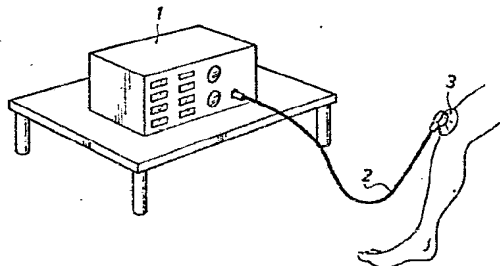
⑦④ Mandataire(s) : Cabinet Beau de Loménie.

⑫⑤ Appareil de laserthérapie externe comportant une ou plusieurs diodes laser dans des ventouses.

⑫⑤ L'invention a pour objet un appareil de laserthérapie  
comportant une ou plusieurs ventouses équipées chacune  
d'une ou plusieurs diodes laser.

Un appareil selon l'invention comporte, d'une part, une ou  
plusieurs ventouses 3 qui sont appliquées au contact de la  
peau d'un patient. Chaque ventouse contient un circuit imprimé  
portant une ou plusieurs diodes laser et, de plus, un condensa-  
teur et un interrupteur électronique à gâchette associé à  
chaque diode. L'appareil comporte un coffret 1 qui contient  
une partie des circuits électroniques qui commandent la charge  
des condensateurs et qui envoient des trains d'impulsions sur  
la gâchette de l'interrupteur électronique. Le coffret 1 est relié  
aux ventouses par un cordon dans lequel passe des conduc-  
teurs électriques et un petit tube souple qui relie les ventouses  
à un appareil d'aspiration.

Une application est le traitement des rhumatismes articu-  
laires.



La présente invention a pour objet des appareils de laserthérapie comportant une ou plusieurs diodes laser dans des ventouses.

Le secteur technique de l'invention est celui de la thérapie externe par laser.

5 On connaît des appareils de traitement thérapeutique par faisceau laser destinés par exemple à irradier une tumeur. Ces appareils utilisent des faisceaux laser de grande puissance qui sont concentrés sur la tumeur à détruire, avec éventuellement un balayage du faisceau laser. Un tel appareil est décrit par exemple dans le brevet  
10 FR. 76/19.997 (ISAKOV V. et Al).

On connaît également des appareils de laserthérapie pour traitement externe qui sont utilisés en dermatologie ou en rhumatologie pour irradier les zones à soigner. Ces appareils comportent une ou plusieurs diodes laser qui émettent des impulsions laser dans l'in-  
15 frarouge et des circuits électroniques d'excitation des diodes laser.

Selon un mode de réalisation connu, les diodes laser sont situées dans le même coffret que les circuits électroniques et l'appareil comporte des conducteurs de lumière en fibres optiques qui véhiculent les impulsions laser entre la diode et la zone à irradier. Ce type  
20 d'appareil présente l'inconvénient qu'une partie de la puissance du faisceau laser est absorbée par la fibre optique qui relie chaque diode à la zone à irradier.

Selon un autre mode de réalisation connu, l'émetteur laser comporte une sonde manuelle dans laquelle se trouve une diode laser  
25 et une partie des circuits d'excitation de celle-ci, ce qui aboutit à une sonde manuelle relativement encombrante, qui doit être tenue manuellement au contact de la zone à irradier pendant toute la durée d'une séance de traitement.

On connaît également des appareils de traitement externe  
30 comportant une sonde laser portée par un bras articulé qui permet de maintenir la sonde laser, comportant une ou plusieurs diodes, au contact de la zone à traiter. Dans ce cas le patient doit rester rigoureusement immobile. Tout mouvement du patient ou tout changement d'orientation de la sonde dirige le faisceau laser en dehors de la  
35 zone à traiter, d'où des échecs.

On connaît également des appareils permettant de balayer la zone à traiter par un faisceau laser qui est dirigé vers celle-ci par des miroirs.



Dans ce cas, les phénomènes de diffraction et de réflexion de la lumière sur les surfaces convexes entraînent des pertes d'énergie importantes et diminuent, de façon sensible l'efficacité du traitement.

5            Cette technique ne permet pas d'atteindre des lésions d'accès difficile.

          L'objectif de la présente invention est de procurer des moyens pour diriger et maintenir un faisceau laser sur une zone externe qui remédient aux inconvénients des dispositifs connus. Le faisceau  
10 laser doit être dirigé perpendiculairement à la surface de la peau.

          Dans certaines pathologies, le patient doit pouvoir changer fréquemment de position pendant l'irradiation. De plus, il est nécessaire dans le traitement de pathologies rhumatismales de traiter plusieurs éléments anatomiques en même temps. Par exemple, en cas de  
15 traitement de lésions ligamentaires et d'insertions tendineuses du genou, il faut traiter simultanément le ligament latéral externe, le ligament latéral interne et la patte d'oie.

          L'incorporation de diodes laser dans des ventouses permet de maintenir les diodes à proximité de la zone à traiter, sans nécessiter aucun opérateur ou aucun appareillage complexe, elle permet de  
20 traiter plusieurs éléments anatomiques en même temps et elle permet également que le patient bouge pendant le traitement.

          Le problème à résoudre est de concevoir des circuits d'excitation d'une diode laser permettant de disposer la diode dans une  
25 ventouse, donc à une certaine distance du coffret contenant les circuits électroniques, tout en excitant efficacement la diode.

          A priori, il pourrait sembler qu'il suffit de disposer la diode laser qui est peu encombrante dans une ventouse et de la relier par un conducteur à des circuits électroniques disposés dans un coffret. Une telle solution ne serait pas possible. En effet, pour qu'une  
30 diode émette un rayonnement laser, il faut l'exciter par des impulsions ayant un front très raide, de l'ordre de la nanoseconde afin d'obtenir une puissance instantanée suffisante pour déplacer les électrons et pour créer l'émission laser.

35            Ces impulsions sont obtenues généralement par la décharge d'un condensateur à travers la diode et la durée du front de décharge dépend donc du produit R.C., c'est-à-dire de la résistance du circuit de décharge du condensateur. Si le condensateur se trouve dans le

coffret, la diode lui est reliée par un conducteur électrique ayant plusieurs mètres de longueur, dont la résistance de décharge est élevée et le front de décharge du condensateur n'est pas suffisamment raide pour provoquer l'émission laser.

5 L'objectif de l'invention est atteint au moyen d'un appareil de laserthérapie externe qui comporte :

- d'une part, une ou plusieurs ventouses destinées à être appliquées et maintenues au contact de la zone à traiter, chaque ventouse contenant un circuit imprimé portant une ou plusieurs diodes laser et portant, en outre, associés à chaque diode, un condensateur et un interrupteur électronique à gâchette qui est monté en série avec ladite diode laser dans un circuit de décharge dudit condensateur;
- et, d'autre part, un coffret qui est relié à chaque ventouse par un cordon dans lequel passe un conducteur électronique permettant de charger lesdits condensateurs sous une faible tension continue, un conducteur permettant d'envoyer des trains d'impulsions de commande sur la gâchette dudit interrupteur et un petit tube souple qui relie ladite ventouse à un appareil d'aspiration situé dans ledit coffret.

20 La présente invention a pour résultat de nouveaux appareils de laserthérapie externe destinés à être utilisés en dermatologie, en rhumatologie ou en traumatologie, pour traiter une ou plusieurs zones localisées de la peau ou une articulation au moyen d'impulsions laser.

25 Les appareils selon l'invention comportant des diodes laser placées dans des ventouses permettent de maintenir ces diodes à une distance déterminée de la peau pendant toute une séance de traitement sans l'intervention d'aucun opérateur.

30 Avantageusement, la surface interne des cavités des ventouses peut être recouverte d'un revêtement réflecteur qui évite des pertes de lumière laser et qui permet de concentrer celle-ci sur une zone de la peau de faible surface grâce à la forme concave de la ventouse et du revêtement réflecteur.

35 Les appareils selon l'invention qui comportent un condensateur et un interrupteur électronique commandé par une gâchette associés à chaque diode laser et disposés à proximité de celle-ci dans la ventouse elle-même permettent d'obtenir une émission laser grâce à la rapidité de la décharge du condensateur bien que celui-ci soit de faible capacité à cause de ses dimensions forcément très réduites et soit

chargé sous une faible tension pour éviter les risques d'électrocution.

Un appareil selon l'invention comportant un interrupteur à gâchette dont les fermetures sont commandées par des trains d'impulsions permet de faire varier la fréquence des impulsions et la durée des trains d'impulsions.

Les appareils selon l'invention permettent de libérer le praticien pendant un traitement laser. Ils permettent de maintenir avec précision le ou les faisceaux laser dirigés sur la lésion à traiter. Ils permettent d'allonger la durée des irradiations, ce qui est primordial dans les cas de pathologies inflammatoires chroniques (rhumatismes) où une quantité minimale d'énergie est nécessaire pour améliorer l'état inflammatoire.

La description suivante se réfère aux dessins annexés qui représentent, sans aucun caractère limitatif, un exemple de réalisation d'un appareil de laserthérapie selon l'invention.

La figure 1 est une vue d'ensemble d'un appareil selon l'invention.

La figure 2 est une coupe transversale d'une ventouse contenant une seule diode laser.

La figure 3 est une coupe transversale d'une ventouse contenant trois diodes laser.

La figure 4 est une représentation d'une partie des circuits d'excitation d'une diode laser.

La figure 5 est un diagramme qui représente la forme des impulsions traversant la diode laser.

La figure 6 est un diagramme qui représente les impulsions de commande de l'interrupteur statique monté en série avec la diode laser.

La figure 1 est une vue d'ensemble d'un appareil destiné à des traitements externes par exemple pour irradier des muscles, des ligaments ou des articulations.

La figure 1 représente par exemple une application à l'irradiation de l'articulation du genou.

Un appareil selon l'invention comporte, d'une part, un coffret 1 qui contient la plus grande partie des composants électroniques nécessaires pour alimenter et exciter une ou plusieurs diodes laser émettant dans l'infrarouge.

De telles diodes sont bien connues ainsi que les circuits d'excitation de celles-ci et il n'est pas nécessaire de les décrire en détail. Le coffret 1 comporte, sur sa face avant, divers appareils de mesure ainsi que des boutons poussoirs qui permettent de commander la mise en route et l'arrêt de l'appareil, lequel peut être commandé automatiquement par une minuterie réglable. On peut également commander la fréquence des trains d'impulsions laser ainsi que le séquençement des trains d'impulsions, c'est-à-dire les intervalles de temps entre les trains d'impulsions successifs.

Le coffret 1 est relié par un cordon 2 ayant plusieurs mètres de long à une ventouse 3 qui est appliquée contre la peau du patient sur la zone à irradier, par exemple sur le genou dans l'exemple représenté. La ventouse 3 contient une ou plusieurs diodes laser et une partie des composants électroniques nécessaires à l'excitation de celles-ci et le cordon 2 contient les conducteurs électriques de liaison avec les circuits électroniques contenus dans la ventouse 3. Le coffret 1 contient également des moyens d'aspiration et le cordon 2 contient un petit tube souple qui relie lesdits moyens d'aspiration aux ventouses 3 pour maintenir celles-ci appliquées contre la peau.

La figure 1 représente un exemple d'un appareil comportant une seule ventouse.

En variante, un même coffret 1 peut comporter plusieurs cordons 2 et plusieurs ventouses 3.

La figure 2 est une coupe axiale d'une ventouse 4. On voit sur cette figure le cordon 2 qui contient un tube d'aspiration 4 et un câble coaxial 5 dans lequel passent les conducteurs électriques.

La ventouse comporte un corps 6 en un matériau élastomère qui délimite une cavité 7, dans lequel débouche le tube d'aspiration 4. Le corps 6 contient, en outre, un petit circuit imprimé 8 qui supporte une diode laser 9 placée dans le fond de la cavité 7 et dans l'axe de celle-ci, de sorte qu'elle est maintenue à une distance déterminée de la peau qui est par exemple de 4 mm. Le circuit imprimé 8 porte également un petit nombre de composants électroniques 10, d'encombrement très réduit, dont la nature et la fonction sont expliquées en référence à la figure 4. Le circuit imprimé 8 et les composants 10 sont noyés dans une matière isolante 6a, par exemple

une résine élastomère.

La figure 3 représente une coupe transversale d'un autre mode de réalisation, dans lequel le circuit imprimé 8 porte plusieurs diodes laser 9 et les composants électroniques 10 associés à chaque diode. Les parties homologues sont représentées par les mêmes repères sur les figures 2 et 3.

On a représenté sur la figure 4 une ventouse dans laquelle la surface interne de la cavité 7, délimitée par la ventouse, porte un revêtement réflecteur 7a, par exemple une peinture réfléchissante, qui évite les déperditions de la lumière laser émise par les diodes et qui permet de concentrer celle-ci sur des zones localisées de la peau.

La figure 4 est un schéma représentant une partie des circuits et des composants électroniques d'un appareil selon l'invention.

Le cadre en traits mixtes 11 représente les composants qui se trouvent sur le circuit imprimé 8 disposé dans la ventouse. Le cadre en traits mixtes 12 représente une partie des circuits qui se trouvent dans le coffret.

La figure 4 représente un exemple de réalisation d'une ventouse comportant une seule diode laser 9. Dans le cas d'une ventouse comportant plusieurs diodes laser, le circuit imprimé logé dans la ventouse porte plusieurs ensembles de composants identiques à ceux qui sont représentés dans le cadre 11.

Chaque diode laser 9 est montée en série avec un interrupteur statique 13 à très faible impédance comportant une gâchette de déclenchement. L'interrupteur 13 est, de préférence un unijonction, mais ce pourrait être un autre interrupteur équivalent, par exemple un thyristor. La diode laser et l'interrupteur 13 sont montés en parallèle avec un condensateur 14.

Lorsque l'interrupteur 13 est fermé, le condensateur 14 se décharge brusquement à travers la diode laser 9. L'impédance de l'interrupteur 13 et de la diode 9 est très faible ainsi que celle du circuit qui les relie au condensateur 14, du fait que celui-ci est situé à proximité de la diode. Il en résulte un temps de décharge très bref, de l'ordre de la nanoseconde. La puissance instantanée qui se décharge à travers la diode laser est donc très élevée malgré la faible tension de charge du condensateur imposée par la sécurité et elle provoque l'émission laser.

La diode laser 9 est montée en série avec plusieurs diodes

15 montées en parallèle. Les diodes 15 évitent des retours de tension vers le coffret 1.

Le condensateur est chargé, par exemple, sous une faible tension continue, par exemple sous une tension de 5,5 volts qui provient du coffret 1 par un conducteur 16 à travers un transistor 17, qui fait fonction de valve évitant que la décharge du condensateur ne puisse se diriger vers le coffret 1.

La gâchette de l'unijonction 13 est connectée sur un conducteur 18 qui la relie à un circuit de mise en forme d'impulsions composé d'un transistor 19 et d'un condensateur 20 qui sont disposés dans le coffret 1. Le circuit de mise en forme reçoit des impulsions 21 en forme de créneaux rectangulaires provenant d'un multivibrateur non représenté.

La durée de ces impulsions est par exemple de 100 nanosecondes et la fréquence de l'ordre de 5000 Hz. Le coffret 1 comporte des moyens électroniques permettant de faire varier la fréquence du multivibrateur en fonction des applications. Il comporte également des moyens pour faire varier la durée des trains d'impulsions et l'intervalle entre trains d'impulsions.

La figure 5 représente l'évolution de la tension au point A de la figure 4, c'est-à-dire de la tension aux bornes de la diode laser. On voit que pendant la décharge du condensateur, cette tension décroît brutalement avec un front descendant très rapide.

La figure 6 représente les impulsions de tension au point B de la figure 4, c'est-à-dire les impulsions émises par le circuit de mise en forme 19, 20 qui commandent les fermetures de l'interrupteur 13 et donc les décharges du condensateur 14.

R E V E N D I C A T I O N S

1. Appareil de laserthérapie externe, caractérisé en ce qu'il comporte :

- d'une part, une ou plusieurs ventouses (3) destinées à être appliquées et maintenues au contact de la zone à traiter, chaque  
5 ventouse contenant un circuit imprimé (8) portant une ou plusieurs diodes laser (9), et portant, en outre, associés à chaque diode, un condensateur (14) et un interrupteur électronique à gâchette (13) qui est monté en série avec ladite diode laser dans un circuit de décharge dudit condensateur;
- 10 - et, d'autre part, un coffret (1) qui est relié à chaque ventouse par un cordon (2) dans lequel passe un conducteur électronique (16) permettant de charger lesdits condensateurs (14) sous une faible tension continue, un conducteur (18) permettant d'envoyer des trains d'impulsions de commande sur la gâchette dudit interrupteur (13)  
15 et un petit tube souple qui relie ladite ventouse à un appareil d'aspiration situé dans ledit coffret.

2. Appareil selon la revendication 1, caractérisé en ce que lesdits interrupteurs électroniques (13) sont des unijonctions.

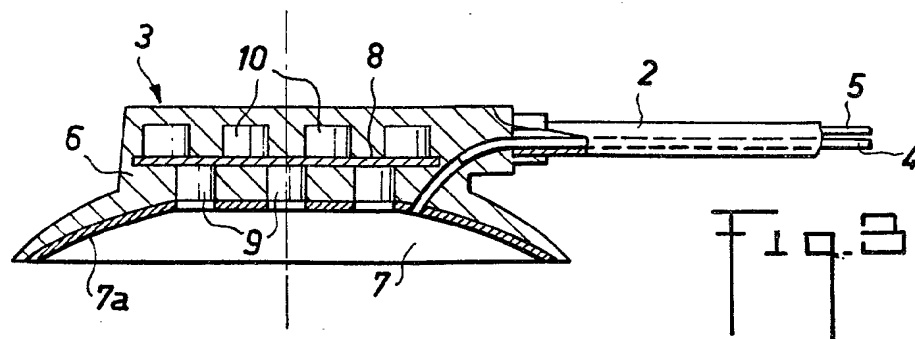
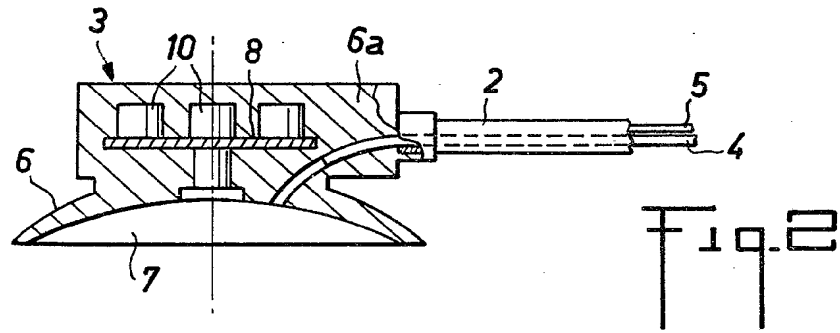
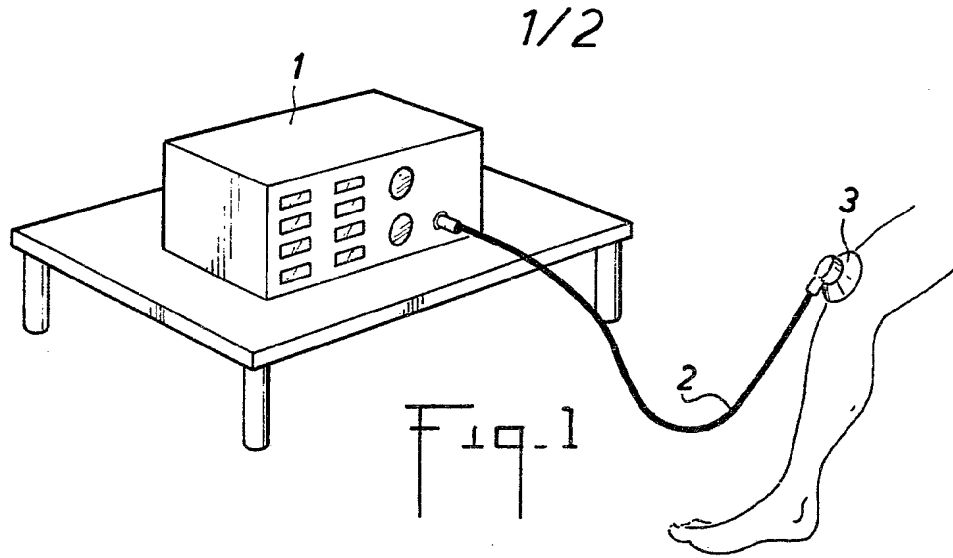
3. Appareil selon l'une quelconque des revendications 1 et  
20 2, caractérisé en ce que lesdites ventouses sont en un matériau élastomère.

4. Appareil selon l'une quelconque des revendications 1 à 3, caractérisé en ce que lesdits circuits imprimés (8) et les composants électroniques (9, 10) portés par lesdits circuits sont noyés  
25 dans une résine isolante (6a).

5. Appareil selon l'une quelconque des revendications 1 à 4, caractérisé en ce que la surface interne des cavités (7) desdites ventouses (3) porte un revêtement réflecteur (7a).

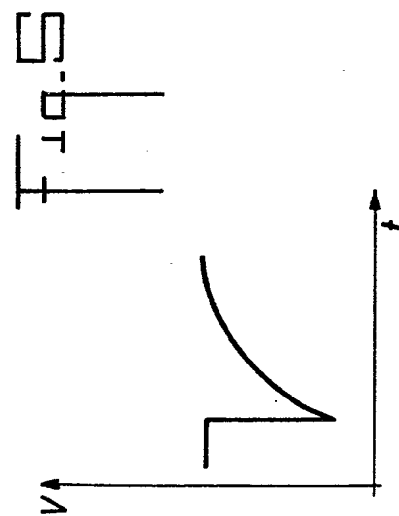
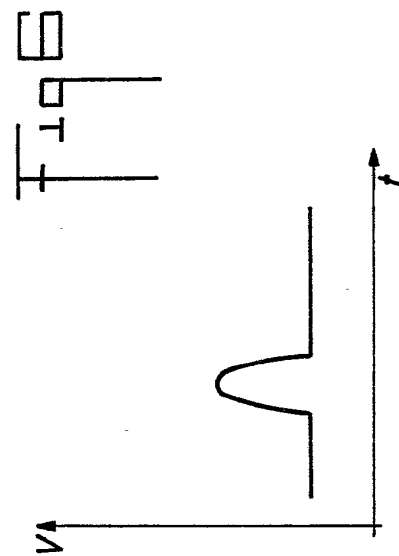
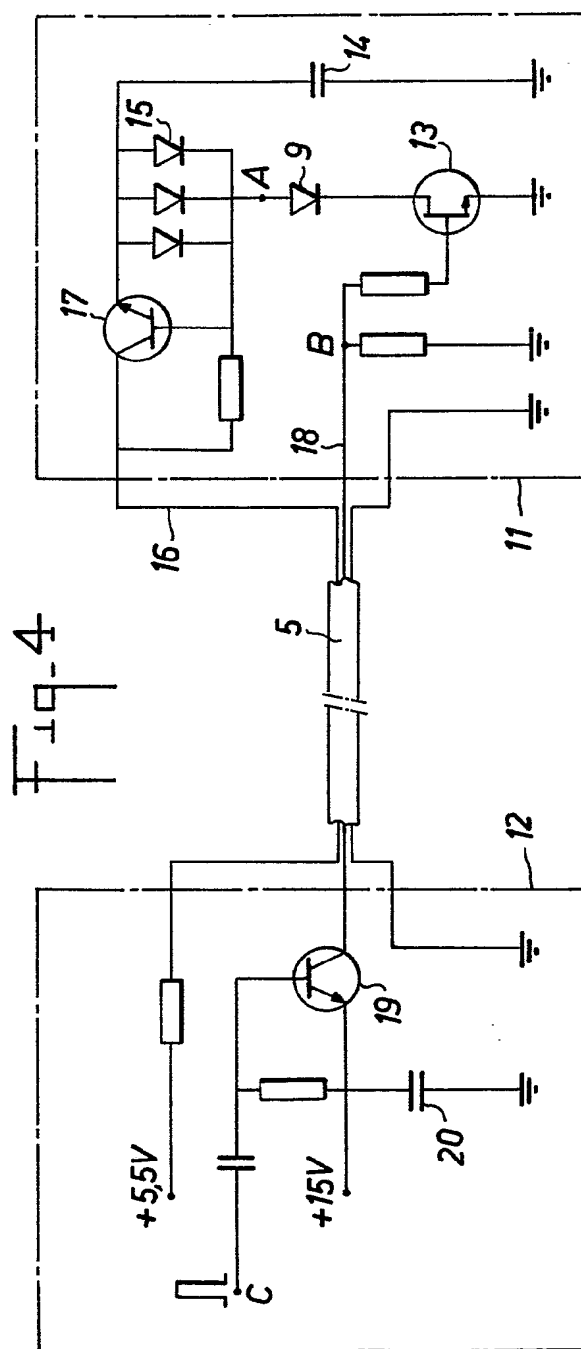
6. Appareil selon l'une quelconque des revendications 1  
30 à 5, caractérisé en ce que ledit coffret contient un multivibrateur qui émet des trains d'impulsions rectangulaires et des circuits (19, 20) de mise en forme desdites impulsions dont la sortie est connectée par un conducteur (18) sur la gâchette dudit interrupteur électronique (13).

7. Appareil selon la revendication 6, caractérisé en ce  
35 que ledit coffret (1) contient des moyens électroniques pour faire varier la fréquence dudit multivibrateur.





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None  
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(54) Improvements in or relating to  
lighting systems for surgical operations

(57) A lighting system for use during surgical operations or examinations comprises a bundle 4 of optical fibres having an intake area into which the light from an ellipsoidal mirror 1 having a lamp therein can be beamed. A concave lens area 3', located in an area facing away from the optical fibre bundle, is co-axially situated adjacent the light intake area of the fibre bundle.

The concave area 3' may be formed by grinding out a portion of a transparent plate 3 and the light from the mirror 1 may be concentrated by an aspheric lens 9 between the mirror and the lens area 3'.

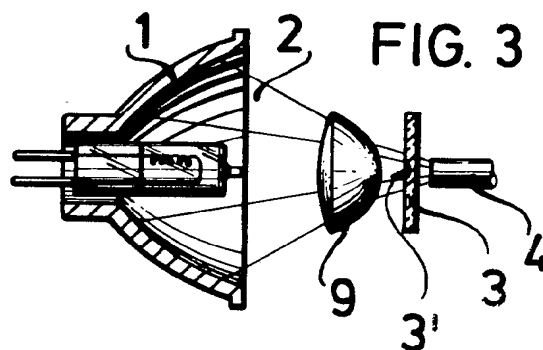


FIG. 1

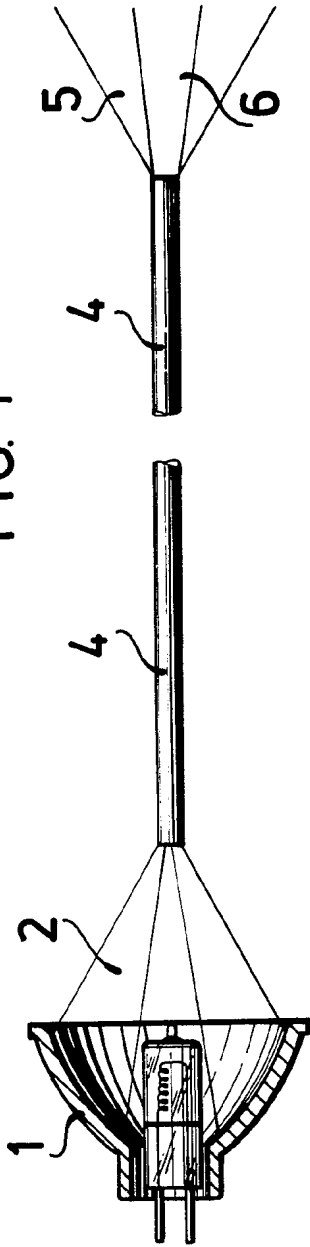


FIG. 1a

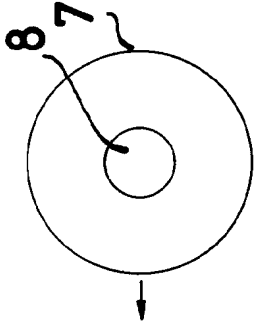


FIG. 2

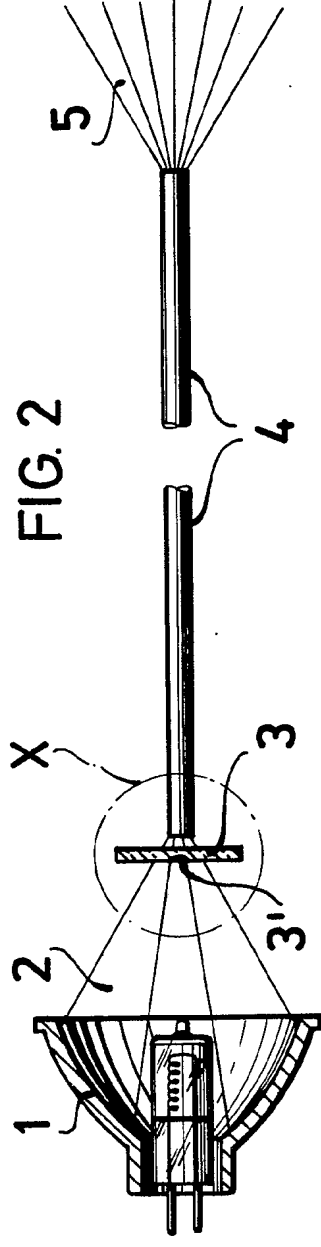


FIG. 2a

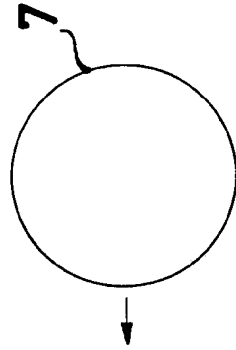


FIG. 2b

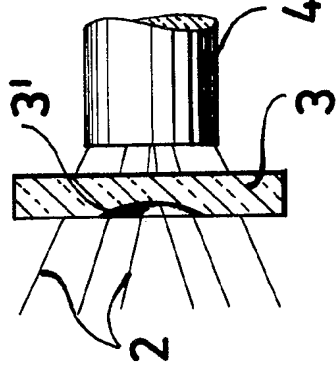


FIG. 2c

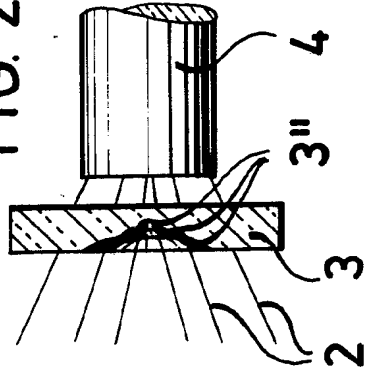
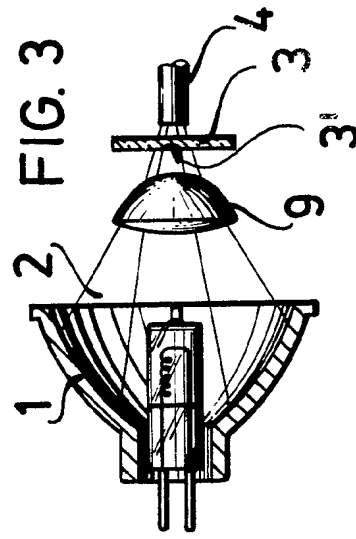


FIG. 3



## SPECIFICATION

**Improvements in or relating to lighting systems for surgical operations**

5 In performing surgical operations, use is made, inter alia, of optical fibre bundles having a small intake area into which the light of an electrical lamp system, particularly a halogen bulb and a post-positioned condenser system or of an ellipsoidal mirror lamp is beamed, for illuminating sections to be examined and operated upon by the surgeon. The ellipsoidal mirror lamp displays the highest efficiency for these purposes, but has the disadvantage that 10 a part of the light beam is shadowed by the bulb and that consequently none but inclined light rays are incident on the end faces of the fibres of the optical fibre bundle. This has the result that the field of illumination at the egress side of the optical fibre bundle has a dark spot in the central portion which 20 obtrudes in very disturbing manner during examination and operation in the illuminated section.

It is therefore an object of the invention to retain the favourable efficiency of ellipsoidal mirror lamps but not to minimise or even eliminate the darkening of the lighting field centre, hereinabove referred to.

Accordingly, the invention consists in a lighting system for surgical examinations and operations comprising an optical fibre bundle having an intake 30 area into which the light of an ellipsoidal mirror lamp can be beamed, wherein a concave lens area located in the area facing away from said optical fibre bundle is co-axially situated forwardly adjacent said light intake area of said optical fibre bundle.

35 The light beams of the ellipsoidal mirror lamp emerging at an angle to the axis of the optical fibre bundle are deflected in the axial direction of the optical fibre bundle by the concave lens area which may be ground-into a small transparent e.g. glass, plate, and penetrate into the optical fibre bundle at 40 right angles to the light intake or ingress area, i.e. the light distribution across the section which is to be illuminated is homogenised, so that the surgical area of the patient's body for examination or operation is illuminated in completely even manner. It will be understood that the radius of the concave lens area as well as its diameter, should be adapted to refractive quotient of the lens and the diameter of the optical fibre bundle.

50 In order that the invention may be more clearly understood, reference will now be made to the annexed drawings which show certain embodiments thereof by way of example and a prior art system for comparison purposes, and in which:-

55 *Figure 1* diagrammatically and in side view shows a known lighting system comprising an ellipsoidal mirror lamp with an optical fibre bundle,

*Figure 1a* shows the examination area produced the system of *Figure 1* in plan view,

60 *Figure 2* shows a similar system except that it incorporates a concave lens area in accordance with the invention,

*Figure 2a* shows the homogenised examination section produced by the system of *Figure 2*,

65 *Figures 2b* and *2c* show the part marked "x" in

*Figure 2* in enlarged form of illustration with a different concave lens, and

*Figure 3* shows a further embodiment representing a modification of the system shown in *Figure 2*.

70 Referring now to the drawings, a known prior-art lighting system for illuminating a surgical section of a patient's body to be examined or operated on is shown in *Figure 1*, and comprises an ellipsoidal mirror lamp 1 i.e. an electrical lamp, particularly a halogen (quartz-iodine) bulb built into a reflector (which may be dichroic), which means its light 2 into the confronting end face of an optical fibre bundle 4 forming an intake or ingress area thereof, this light however emerging as a beam 5 with a dark central 80 portion 6, the dark portion appearing as a dark spot in the illuminated examination area 7 as shown in *Figure 1a*.

The avert this dark spot 8, which is very troublesome during an examination or operation, a concave lens area whose concave side is turned away from the end face of the optical fibre bundle, is joined e.g. by being adhered, to the light intake or ingress surface area of the optical fibre bundle 4, or positioned in direct contiguity in front of the light ingress surface, as shown in *Figure 2*. According to the embodiment illustrated, this concave lens area is formed in that face of a small transparent plate, e.g. a small glass plate 3, which faces away from the optical fibre bundle 4. The area is formed by grinding a section co-axial with respect to the optical fibre bundle, the radius of said section being so selected as a function of the refractive index that the light beam otherwise incident at an angle on the beam reception surface of the optical fibre bundle from the ellipsoidal mirror lamp, are refracted and beamed at right angles into the beam reception surface of the light conductor 4. The surgical area 7 for examination which is to be illuminated is lit evenly as shown in *Figure 2a*, and the light of the lamp 1 is homogenised in the area for examination. In this connection, the concave lens area 3' is selected to have a smaller diameter than the diameter of the optical fibre bundle 4, since light would otherwise be lost for the examination.

100 As shown in *Figure 2c*, the concave lens area 3'' may comprise several concentric annular concave lenses of different radius. Fibre bundles may consequently be applied, which have diameters adapted to these annular concave surfaces.

115 In another embodiment shown in *Figure 3*, an aspheric lens 9 is located between the ellipsoidal mirror lamp 1 and the lens area 3' and the optical fibre bundle so as to concentrate the light onto the lens area.

120 The concave lens area need not be formed in a transparent plate but may in fact take the form of a discrete concave lens as will be apparent to those skilled in the art to which the invention relates. For this reason it is believed unnecessary to illustrate it.

## 125 CLAIMS

1. A lighting system for surgical examinations and operations, comprising an optical fibre bundle having an intake area into which the light of an

ellipsoidal mirror lamp can be beamed wherein a concave lens area located in the area facing away from said optical fibre bundle is co-axially situated forwardly adjacent said light intake area of said

5 optical fibre bundle.

2. A lighting system as claimed in claim 1, wherein the concave lens area is part of a concave lens.

3. A lighting system as claimed in claim 1, wherein the concave lens area is an area ground into a transparent plate.

4. A lighting system as claimed in claim 3, wherein the concave lens area comprises several concentric concave ground sections of different

15 radius.

5. A lighting system as claimed in any of the preceding claims, wherein an aspheric lens acting as a condenser lens is interposed between the mirror lamp and the concave lens area, so as to increase the

20 light density.

6. A lighting system substantially as hereinbefore described with reference to Figures 2, 2a and 2b of the accompanying drawings.

7. A lighting system substantially as hereinbefore described with reference to Figure 2c of the

25 accompanying drawings.

8. A lighting system substantially as hereinbefore described with reference to Figure 3 of the accompanying drawings.

# (12) UK Patent Application (19) GB (11) 2 059 053 A

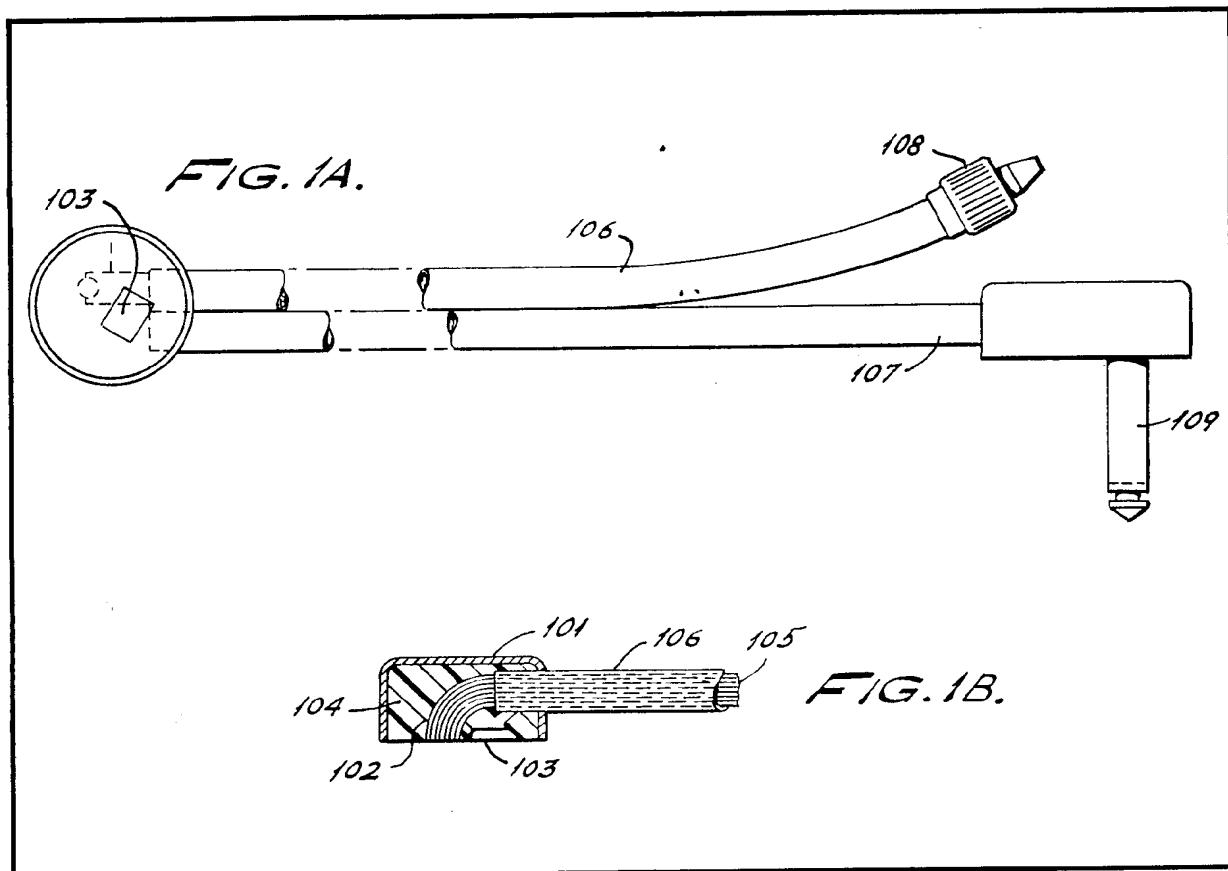
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G11 G14 G6 MQ P10  
R6 R7 S1 T15 T27 T3  
(56) Documents cited  
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GB 987504  
(58) Field of search  
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(71) Applicant  
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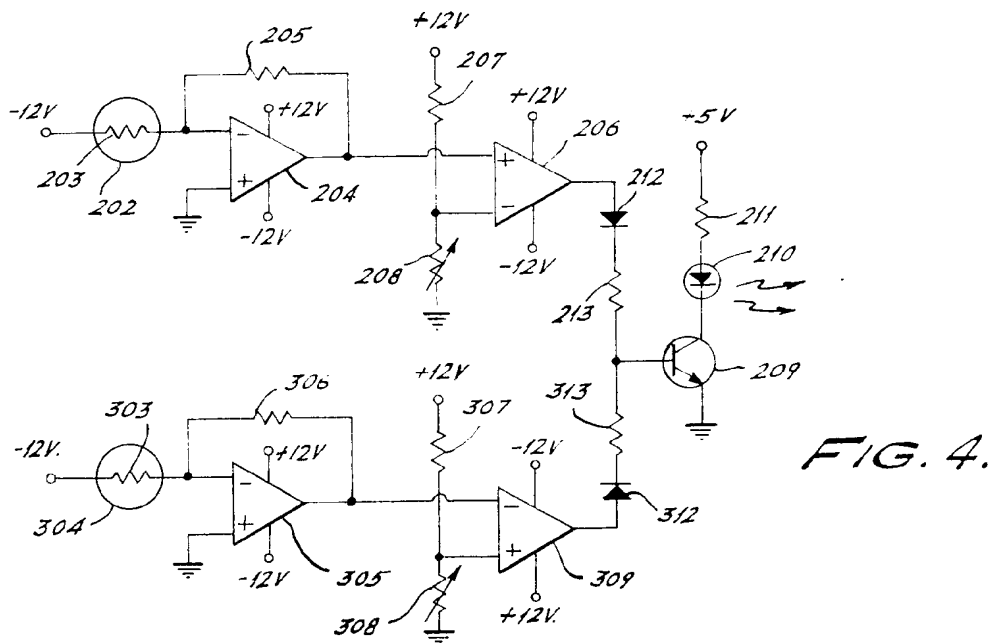
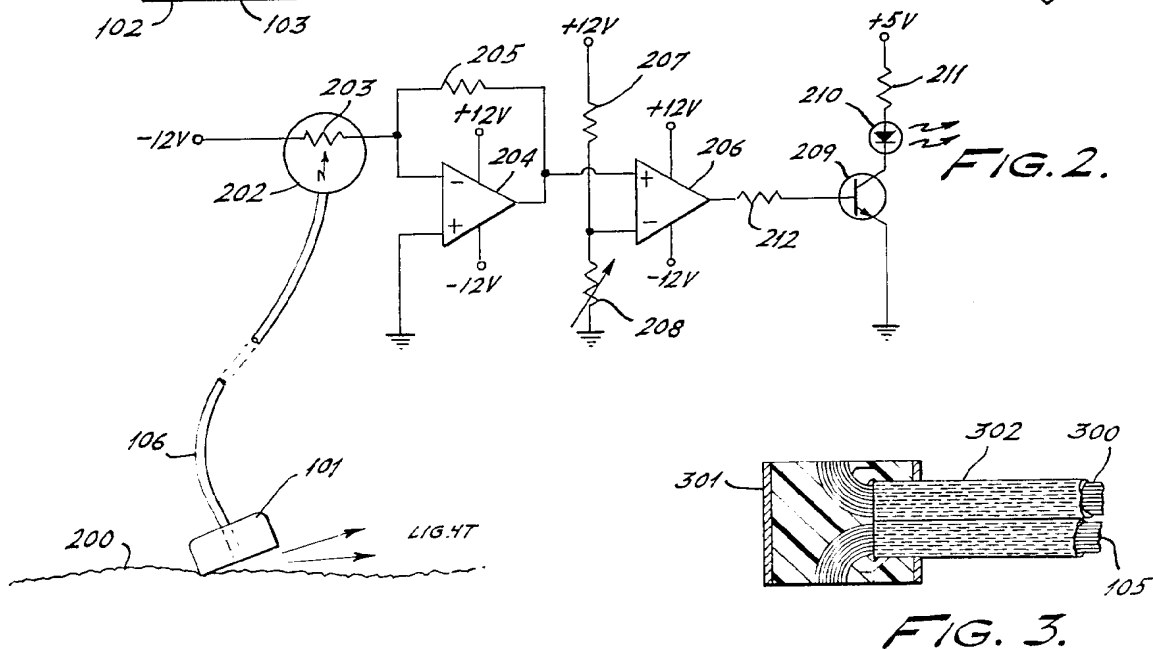
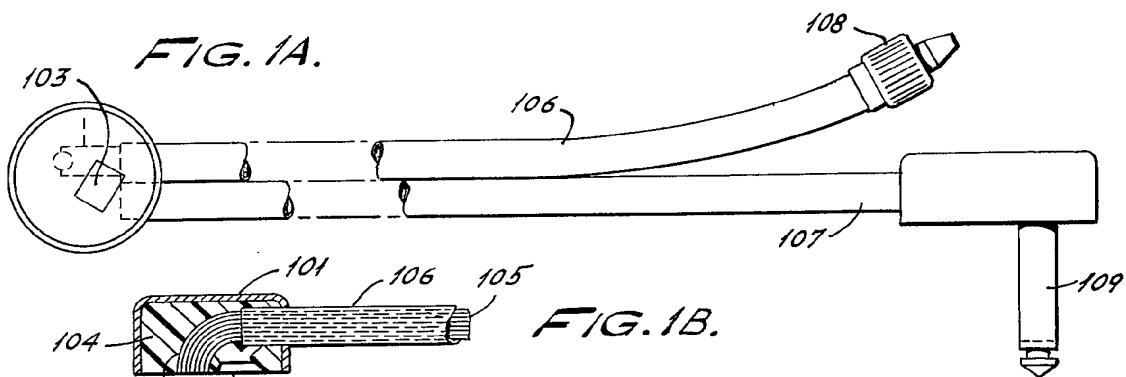
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## (54) Photo-electric detection of probe dislodgement

(57) When a probe having a contact surface adapted to be placed on a surface of the body to monitor or control a body function is dislodged from the body, an increased radiation level impinges on the contact surface and radiation receiving means 105 located in the contact surface sense the increased radiation level and provide an indication

of probe dislodgement. A skin temperature probe having a thermistor 103 at the skin contact face has a bundle of optical fibres 105 ending at that face for detection of light when the probe is dislodged, and may have a second bundle of fibres ending at the opposite face for detection of covering of the probe e.g. by a blanket.





## SPECIFICATION

### Apparatus for detecting probe dislodgement

5 The invention relates to skin contact probes, and more particularly to apparatus for detecting dislodgement of such probes. Although the invention will be described in connection with a probe having means for sensing body temperature, it will be apparent that the invention has broader application. The invention may be extended to probes which monitor other body functions and to probes which control or influence a body state or condition.

15 As an example, several devices, in common use, provide thermal environmental control by positioning temperature probes which are intended to be maintained in intimate contact with the skin and by utilizing such probes to control operation of a heater for incubators and radiant warmers. Typically, such probes involve a thermoelectric transducer mounted on a skin contact surface. Electrical signals from the transducer are utilized for heater control. In such instances, it is essential to maintain intimate contact between the probe and the skin, and particularly to maintain contact with the skin and the rather sensitive thermoelectric transducer. Should the probe become completely dislodged, there is the possibility of having it contact a hot or cold surface, with consequent derangement of the thermal environment. Even a small discontinuity between probe and skin, short of total dislodgement, can work adversely to proper control of the thermal environment. Furthermore, it is important to know when a system, provided for identifying probe dislodgement, is rendered ineffective to perform this function.

40 It is an object of the present invention to provide apparatus for detecting dislodgement of skin contact probes, and more particularly to detect even rather slight discontinuities between the probe and the skin.

45 It is a more particular object of the present invention to provide apparatus which senses probe dislodgement based on the receipt of ambient light, or radiation from specific sources, at the skin contact surface of the probe when mounted on the skin.

50 It is a still further object that the apparatus for sensing probe dislodgement by light reception being capable of discriminating between light associated with the dislodgement, and light which arrives through skin translucence during adequate contact, and furthermore that it does so independently of the pigmentation of the skin of the subject.

60 Yet another object of the present invention is to provide a probe which develops an indication when the probe is covered and thereby prevented from sensing dislodgement.

65 The present invention senses increased radiation levels attendant to dislodgement of a

contact probe from a skin surface with which it is placed in contact. Transducer means having a light receiving portion located in the skin contact surface of the probe sense the increased radiation level impinging on the probe contact surface when the probe is dislodged and a radiation signal is developed representative of the radiation level impinging upon the contact surface. When a threshold is exceeded, indicating dislodgement, an alarm circuit is energized. The alarm threshold may be adjusted to meet varying conditions of ambient light, skin pigmentation and the like.

70 According to the invention, apparatus for sensing probe dislodgement comprises a probe housing having a contact surface adapted for contact with a body; transducer means having a radiation receiving portion located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and for developing a radiation signal representative of the radiation level impinging upon said contact surface; means for supplying a threshold signal representative of a predetermined radiation level less than said increased radiation level impinging upon said contact surface when said probe is dislodged from said body, and alarm means responsive to said radiation signal and said threshold signal for developing an indication when said radiation level impinging upon said contact surface exceeds said predetermined radiation level.

100 The invention may also provide a probe for sensing a body function, the probe comprising a probe housing having a contact surface arranged to contact a body; a sensor located in said contact surface and responsive to said body function; radiation receiving means located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and means emanating from said housing for transmitting the outputs of said sensor and said radiation receiving means to a distant location.

110 The invention may particularly provide apparatus for sensing skin contact probe dislodgement, the apparatus comprising housing means defining a skin contact surface for said probe; photo-receptive means located on said skin contact surface of said housing means; alarm means, energized by reception by said photo-receptive means of light, having an intensity exceeding a predetermined level, said alarm means being placed remotely from said housing means, and photo-transmitting means extending out from said housing means for connecting said housing means, photo-receptive means and said alarm means.



Two embodiments of a probe and associated circuitry in accordance with the invention are now described by way of example with reference to the accompanying drawings, in which:—

*Figures 1a and 1b* show, respectively, a bottom view and a side cutaway view of a probe embodying the principles of the present invention;

*Figure 2* shows a schematic circuit for detecting and displaying probe dislodgement conditions;

*Figure 3* is a side cutaway view of another embodiment of a probe embodying the principles of the present invention; and

*Figure 4* shows a schematic circuit useful with the probe of *Fig. 3* for detecting and displaying probe dislodgement conditions.

Referring first to *Figs. 1a and 1b*, there is shown a skin temperature probe embodying the principles of the present invention. In the *Figures*, a thermistor 103 is employed, as is conventional in thermal sensing skin contact probes. Electrical signals from the thermistor 103, corresponding to skin temperature changes, are coupled via cable 107 and jack 109 to the heater controls, there to enable appropriate changes in the thermal environment to correspondingly increase or decrease the skin temperature of the subject. The probe is defined by an outer housing 101, which is shown to have a generally cylindrical configuration, but which, it will be appreciated, may vary in accordance with the characteristics of the subject and the needs of the designer. The lower, or skin contact surface of the probe, carries not only the thermistor 103, but also the end of a fibre-optic bundle 105, suitable optically prepared for receipt and conveyance of impinging light, be it ambient light or light from a specific source.

Fibre-optic bundle 105 passes through a rigid elbow 102 directing the bundle toward and through the outside of the housing 101. A potting compound 104, such as epoxy resin or the like, not only holds the fibre-optic bundle 105 and the thermistor 103 in place within the housing 101, but also defines generally the skin contact surface thereof and holds the position of the optically prepared end of fibre-optic bundle 105 and the thermistor 103 thereon. A hollow conduit 106 encloses the fibre-optic bundle 105 between the probe, monitor and alarm circuitry described below. A suitable connector 108 is provided at the free end of conduit 106.

In the embodiment shown, *Figs. 1a and 1b*, the fibre-optic bundle 105 is maintained clustered together, generally at the centre of the skin contact surface, and in relatively close proximity to the thermistor 103. The housing 101 and the conduit 106 are opaque, whereby ambient light will not impinge on the sides of the fibre-optic bundle 105, and the only light in bundle 105 will arrive from the

input end of the probe-skin contact surface. Likewise, loss of light in transmission along bundle 105 is thereby prevented.

In an alternative embodiment, respective portions of the optical fibres 105 may be arrayed at disparate points on the skin contact surface, for example at the periphery thereof or surrounding the thermistor 103. In such event, the elbow casing 102 may not be required, with the respective fibres converging into a bundle near the exit from the housing 101, thence traversing the interior of conduit 106.

Any of the embodiments of the present invention may employ an extensive variety of configurations for the probe 101, including for example, the entire probe structure, corresponding to housing 101 and potting compound 104 may be fabricated of an integral moulding, about the optical interface at the termination of bundle 105, and the thermistor 103. Many commercially available materials are suitable for such an application, polyurethane rubber moulding compound being one of them. Moreover, a separate light source may be provided in proximity to the probe 101 to provide a source of light for the functioning of the monitor and alarm of the invention especially when there is an absence of ambient light. Alternatively, the separate light source may be remote from the probe and the light conducted to the probe through a fibre-optic bundle.

As shown in *Fig. 2*, the probe 101 may be disposed against the skin 200 of a subject in a dislodgement position whereby ambient light impinges on the skin contact surface of the probe. The apparatus for holding the probe in place is not shown. This may involve tape, belts, straps, or the like. In such an event, light received at the optical interface as a result of dislodgement is conveyed via the fibre-optic bundle 105 within conduit 106 to an optical detector 203. The circle identified by reference number 202 represents a receptacle which receives and engages connector 108 of conduit 106.

Numerous types of optical detectors 203 are available, each with its own respective operational characteristics. The preferred embodiment herein utilizes a detector 203 having a preference for sensitivity, rather than operational speed. Generally, all types of commercially available photosensors function within a time responsiveness range satisfactory to render a timely alarm in response to the light impinging on the probe bundle 105 upon dislodgement. However, some photoelectric transducers possess sensitivity characteristics which are preferable to others for purposes of the present invention. In a preferred embodiment, the photosensor 203 is a photoconductive cell of the cadmium sulphide type, for example, those available under the commercial designation "Clairex CL 909L"

cell. It is to be understood, however, that depending on the system to which the invention is applied, and the particular sensitivity/responsiveness constraints thereon, the photo-detector 203 may also be embodied as a

photo-Darlington transistor, a PIN transistor, a PIN silicon photo diode, a photovoltaic cell, or the like.

The photodetector 203 is connected to a — 12 volt supply. A current change produced by a change in the conductivity of the photo-detector 203 when energized by light from the fibre-optic bundle is coupled to the inverting input of an amplifier 204, the non-inverting input of which is held at ground, that is earthed. Amplifier 204 is arranged with resistor 205 in a feedback configuration to the inverting input. The amplifier 204 fulfills the function of a linear detection of current from photosensor 203, and therefore preferably involves strong current sensing capabilities with negligible bias currents over the operating temperature involved. In a preferred embodiment, amplifier 204 is implemented by a high input impedance operational amplifier such as those having junction field-effect transistor (JFET) input stages, for example those available under the commercial designation "National LF355" integrated circuits.

The output of amplifier 204 is coupled to the non-inverting input of a comparator-amplifier 206 which functions as a threshold circuit. The inverting input of amplifier 206 is coupled to the central point of a voltage divider comprising resistors 207 and 208 connected between a + 12 voltage supply and ground. Hence, the signal at the non-inverting input of amplifier 206 will cause amplifier 206 to go positive depending upon input signal amplitude relative to the threshold voltage from divider 207 and 208. The threshold voltage is set to represent a predetermined light level corresponding to the level of background light reaching the end of fibre-optic bundle 105 when the skin contact surface of the probe is in contact with the skin. Amplifier 206 is the type commercially available under the trade designation "LM301".

Comparator-amplifier 206 has its output coupled through a resistor 212 to the base of a transistor 209, which has a light emitting diode 210 in its collector circuit. The light emitting diode 210 is connected in series with a resistor 211 between a + 5 volt supply and the collector of the transistor 209 while the emitter of this transistor 209 is tied to ground, i.e. it is earthed.

When the voltage from amplifier 204 to comparator 206 exceeds the threshold voltage established by the divider 207 and 208 transistor 209 is turned on, and diode 210 is switched into the conducting state. The light emitted serves to alarm the condition of dislodgement, indicating to the operator of the system that the probe 101 has become dis-

lodged from the skin 200.

Resistor 208 is shown as a variable resistor, thereby affording an adjustment facility to the threshold of comparator 206, in order to account for anticipated ranges of ambient light, circuit sensitivity-parameters, and skin pigmentation and translucence characteristics. Depending upon the application desired, the resistor 208 may be preset during a calibration process, or may be variable in accordance with the needs of the operator.

It is to be understood that audible alarm systems may be utilized in substitution for, or in conjunction with the light emitting diode 210.

The invention operates wherein, should the probe 101 become partially dislodged from the skin 200, ambient light will impinge on the skin contact surface of the probe, and will be conveyed by the fibre-optic bundle 105 within conduit 106 to the photosensor 203. An electrical signal is produced thereby, processed at amplifier 204 and comparator 206, and the alarm diode 210 is energized upon the activation of transistor 209.

Fig. 3 shows a second embodiment of a probe constructed in accordance with the present invention and provided with means for sensing when the probe is covered so as to be shielded from sources of light and rendered ineffective. In use, a body probe may become covered by a blanket, bandage or piece of equipment. When this occurs, an optical sensing technique for detecting probe dislodgement will not function properly, if at all, if the light sensor is shielded from the ambient light or a specific source of light. In the Fig. 3 probe, a second fibre-optic bundle 300 is provided which opens into the top surface of probe housing 301. A hollow conduit 302 encloses fibre-optic bundle 300 between the probe and the alarm circuitry shown in Fig. 4.

Under normal operating conditions, fibre-optic bundle 105 transmits no light or very little light while the contact surface of housing 301 is in contact with the skin. At the same time fibre-optic bundle 300 transmits the light impinging upon the top surface of housing 301. If the probe becomes covered by a blanket or the like, the light level transmitted by fibre-optic bundle 300 drops significantly to the level of light which penetrates the covering.

Much of the circuit shown in Fig. 4 corresponds to the circuit of Fig. 2 and like components have been given the same reference numerals. The lower branch of the Fig. 4 circuit, added to develop an alarm indication when the probe is shielded from its light source, functions in a manner generally similar to the upper branch.

Light received at the top of probe housing 301 is conveyed via fibre-optic bundle 300 within conduit 302 to an optical detector 303.

The circle identified by reference number 304 represents a receptacle which receives and engages the free end of conduit 302.

Optical detector 303 is connected to a  
5 — 12 volt supply. A circuit change produced by a change in the conductivity of optical detector 303 when energized by light from the fibre-optic bundle is coupled to the inverting input of an amplifier 305, the non-inverting input of which is held at ground, i.e., it is earthed. Amplifier 305 is arranged with a resistor 306 in a feedback configuration to the inverting input. Amplifier 305 preferably is similar in construction and operation to amplifier 204.  
15

The output of amplifier 305 is coupled to the inverting input of a comparator-amplifier 309 which functions as a threshold circuit. The non-inverting input of amplifier 309 is coupled to the central point of a voltage divider comprising resistors 307 and 308 connected between a + 12 volt supply and ground. With this arrangement, a signal at the inverting input of amplifier 306 will drive the amplifier output negative. This corresponds to light being detected by optical detector 303 which indicates that the probe is not covered and operating as expected. When the amplitude of the signal at the inverting input of amplifier 309 falls below the threshold voltage established by divider 307 and 308, amplifier 309 operates to develop a positive output signal. This corresponds to little, if any, light being detected by optical detector  
30 303 which indicates the the probe is covered or shielded from light. The threshold voltage at the junction of resistors 307 and 308 is set to represent a predetermined light level corresponding to the level of light impinging upon the end of fibre-optic bundle 300 when the probe is uncovered. This threshold voltage may be set so that more than only a slight decrease in light level impinging upon the top surface of the probe is required to operate amplifier 309. The setting of resistor 308 is determined by the degree of decrease in light level for which it is desired to set off the alarm. Amplifier 309 preferably is similar in construction and operation to amplifier 206.  
45

The output of comparator-amplifier 206 is coupled to the base of transistor 209 through a diode 212 and a resistor 213. The output of comparator-amplifier 309 is coupled to the base of transistor 209 through a diode 212 and a resistor 313. The arrangement is such that when either or both comparator-amplifier 206 and comparator-amplifier 309 develop a positive output signal, transistor 209 conducts and light emitting diode 210 is energized. In particular, amplifier 309 develops a positive output signal whenever the probe is covered and the signal at the inverting input to amplifier 306 is below the threshold amplitude.  
60

Thus, regardless of the output from amplifier  
65 206, light-emitting diode 210 will be ener-

gized whenever the probe is covered. If the probe remains uncovered, but becomes dislodged from the body, an input current increase to the non-inverting input of amplifier 206 will produce an output which causes light-emitting diode 210 to become energized. Whether the alarm is set off because of probe dislodgement or probe covering, the system succeeds in catching the attention of someone who can determine which of the two possibilities caused the alarm.  
70 75

Although the invention, as described, contemplates the detection of ambient light, detectors which are selectively responsive to only a portion of the light spectrum (e.g. infra-red) may be employed and, likewise, the radiation source may be of a more narrow bandwidth.  
80

As stated previously, the present invention has broader application than a skin contact temperature probe. The invention may be applied to other body surface probes which monitor or control other body functions or to probes which penetrate the body. For example, the dislodgement or partial withdrawal of an intravenous feed needle, designed to have a contact surface, may be detected by incorporating the principles of the present invention.  
90

While the embodiments of the probe illustrated in Figs. 1a, 1b and 3 show the use of fibre-optic bundles which transmit light to a distant alarm circuit at which photosensors convert the light to electrical signals, other electro-optical techniques may be employed in practicing the present invention. For example, photocells may be located in the probe contact surface and in the upper housing surface to receive the light and develop electrical signals which are transmitted to the distant alarm circuit.  
100 105

The foregoing has set forth exemplary and preferred embodiments of the present invention. It will be understood, however, that numerous alternative embodiments will occur to those of ordinary skill in the art without departure from the spirit or scope of the present invention.  
110

#### 115 CLAIMS

1. Apparatus for sensing probe dislodgement comprising a probe housing having a contact surface adapted for contact with a body; transducer means having a radiation receiving portion located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and for developing a radiation signal representative of the radiation level impinging upon said contact surface; means for supplying a threshold signal representative of a predetermined radiation level less than said increased radiation  
120 125 130

level impinging upon said contact surface when said probe is dislodged from said body, and alarm means responsive to said radiation signal and said threshold signal for developing an indication when said radiation level impinging upon said contact surface exceeds said predetermined radiation level.

2. Apparatus according to Claim 1 wherein said predetermined radiation level corresponds to the level of background radiation reaching said radiation receiving portion when said contact surface is in contact with said body.

3. Apparatus according to Claim 1 or 2 wherein said alarm means includes a light-emitting device which is energized when said radiation level impinging upon said contact surface exceeds said predetermined level.

4. Apparatus according to Claim 1 wherein said transducer means include light-responsive means for sensing light impinging upon said contact surface and developing a light signal representative of the light level impinging upon said contact surface.

5. Apparatus according to Claim 4 wherein said light responsive means include a fibre-optic bundle having an input end in said contact surface and an output end distant from said contact surface, and a photo-detector positioned at said output end of said fibre-optic bundle and responsive to light transmitted from said contact surface by said fibre-optic bundle.

6. Apparatus according to Claim 1 wherein said apparatus also includes a thermistor for sensing the temperature of said body and developing a signal representative of said temperature.

7. A probe for sensing a body function comprising a probe housing having a contact surface arranged to contact a body; a sensor located in said contact surface and responsive to said body function; radiation receiving means located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and means emanating from said housing for transmitting the outputs of said sensor and said radiation receiving means to a distant location.

8. A probe according to Claim 7 wherein said sensor is a thermistor which develops a signal representative of the temperature of said body and said transmitting means includes an electrical connection for conducting said signal to said distant location.

9. A probe according to Claim 7 or 8 wherein said transmitting means includes a fibre-optic bundle which transmits said radiation impinging upon said contact surface to said distant location.

10. Apparatus for indicating the dislodgement of an article from a body surface, said

apparatus comprising first transducer means having a radiation receiving portion located in a contact surface of said article adapted for contact with said body surface for sensing an increased radiation level impinging upon said contact surface when said article is dislodged from said body surface and said contact surface is exposed to said increased radiation level, and for developing a first radiation signal representative of the radiation level impinging upon said contact surface; second transducer means having a radiation receiving portion located in a second surface of said article removed from said contact surface for sensing a decreased radiation level impinging upon said second surface when said article is covered and said second surface is exposed to said decreased radiation level, and for developing a second radiation signal representative of the radiation level impinging upon said second surface; means for supplying a first threshold signal representative of a first predetermined radiation level less than said increased radiation level impinging upon said contact surface when said article is dislodged from said body; means for supplying a second threshold signal representative of a second predetermined radiation level greater than said decreased radiation level impinging upon said second surface when said article is covered, and alarm means responsive to said first and second radiation signals and said first and second threshold signals for developing an indication where said radiation level impinging upon said contact surface exceeds said predetermined first radiation level or said radiation level impinging upon said second surface falls below said predetermined second radiation level.

11. Apparatus according to Claim 10 wherein said predetermined first radiation level corresponds to the level of background radiation reaching said radiation receiving portion of said first transducer means and said predetermined second radiation level corresponds to the level of radiation impinging upon said second surface when said article is uncovered.

12. Apparatus according to Claim 11 wherein said alarm means include a light-emitting device which is energized when said radiation level impinging upon said contact surface exceeds said background radiation or said radiation level impinging upon said second surface falls below the level or radiation impinging upon said second surface when said article is uncovered.

13. Apparatus according to Claim 12 wherein said second surface is on the opposite side of said article from said contact surface.

14. Apparatus according to Claim 13 wherein said first and second transducer means include light-responsive means for sensing light impinging upon said contact

surface and said second surface.

15. Apparatus according to Claim 14 wherein said first transducer means includes a first fibre-optic bundle having an input end on said contact surface and an output end distant from said contact surface and a first photo-detector positioned at said output end of said first fibre-optic bundle and responsive to light transmitted from said contact surface by said first fibre-optic bundle; and said second transducer means includes a second fibre-optic bundle having an input end in said second surface and an output end distant from said second surface and a second photo-detector positioned at said output end of said second fibre-optic bundle and responsive to light transmitted from said second surface by said second fibre-optic bundle.

16. A probe for sensing a body function comprising a probe housing having a contact surface arranged to contact a body and a second surface spaced from said contact surface; a sensor located in said contact surface and responsive to said body function; first radiation receiving means located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level; second radiation receiving means located in said second surface for sensing a decreased radiation level impinging upon said second surface when said article is covered and said second surface is exposed to said decreased radiation level; and means emanating from said housing for transmitting the outputs of said sensor and said first and second radiation receiving means to a distant location.

17. A probe according to Claim 16 wherein said sensor is a thermistor which develops a signal representative of the temperature of said body and said transmitting means include an electrical connection for conducting said signal to said distant location.

18. A probe according to Claim 16 or 17 wherein said transmitting means includes first and second fibre-optic bundles which transmit said radiation impinging upon said contact surface and said second surface to said distant location.

19. Apparatus for sensing skin contact probe dislodgement comprising housing means defining a skin contact surface for said probe; photo-receptive means located on said skin contact surface of said housing means; alarm means, energized by reception by said photo-receptive means of light, having an intensity exceeding a predetermined level, said alarm means being placed remotely from said housing means, and photo-transmitting means extending out from said housing means for connecting said housing means, photo-receptive means and said alarm means.

20. Apparatus as claimed in Claim 19

wherein said alarm means comprises a transducer means for converting light, received from said photo-receptive means, to an electrical signal, and circuit means for detecting said electrical signal and for displaying a condition corresponding to a change in surface contact.

21. Apparatus as claimed in Claim 20 wherein said photo-receptive means comprises a fibre-optic bundle extending to said transducer from said photo-receptive means, and an opaque conduit surrounding said fibre-optic bundle.

22. Apparatus as claimed in Claim 21 wherein said photo-receptive means includes an optically polished fibre-optic end.

23. Apparatus as claimed in Claim 22 wherein said circuit means includes a threshold detection circuit, responsive to said transducer electrical signal, said threshold corresponding to the level of background light reaching said photo-receptive means when there is intimate contact between the patient's skin and said skin contact surface, and light emitting alarm means energized by said threshold detection circuit.

24. Skin-contacting or other body-contacting probe and a circuit for detecting probe dislodgement substantially as described herein with reference to Figs. 1a and 1b and Fig. 2 of the accompanying drawings.

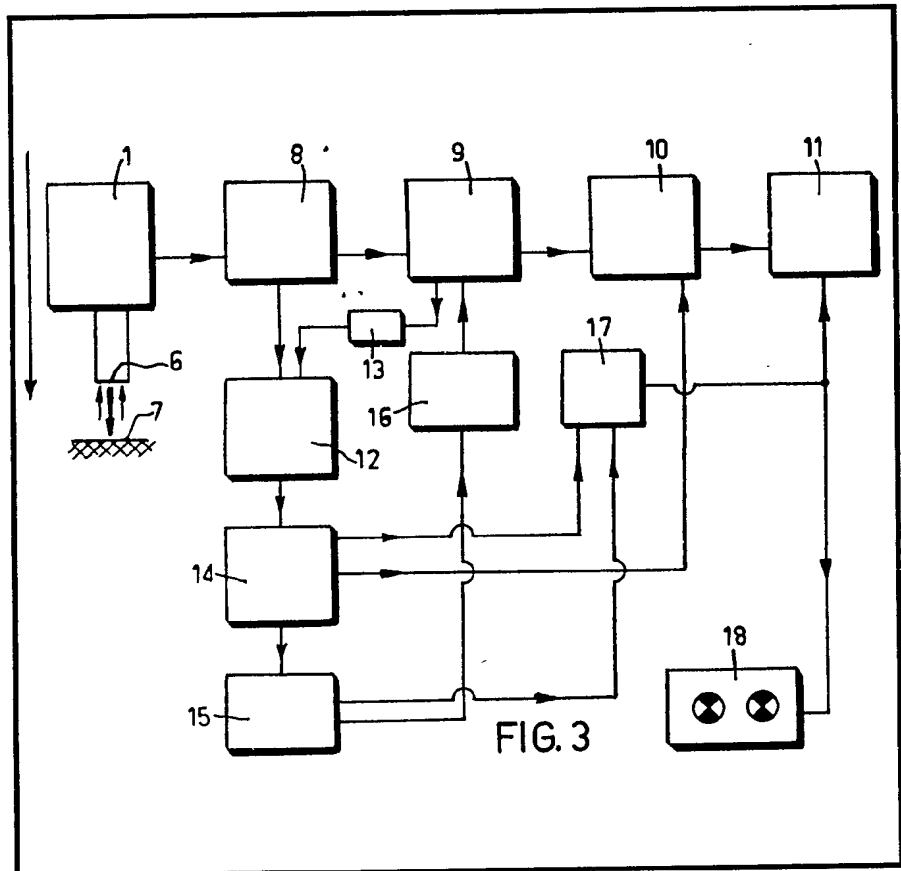
25. Skin-contacting or other body-contacting probe and a circuit for detecting probe dislodgement substantially as described herein with reference to Figs. 3 and 4 of the accompanying drawings.

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**(54) Process and apparatus for making a numerical determination of the colour, or of a colour change of an object**

(57) A coaxial optical fibre bundle assembly 6, carrying emitted light from a light source and receiving light which has been returned by an object illuminated from said light source, is moved towards the object 7 to cause the intensity of the received light, as detected by a phototransistor in light emitter-receiver unit 1, to attain maximum value which is amplified and held as a display on digital voltmeter 11. Comparison of the held value with the corresponding held maximum value resulting from a similar determination made of either a different object or the same object after a colour change can thus be made on a numerical basis.



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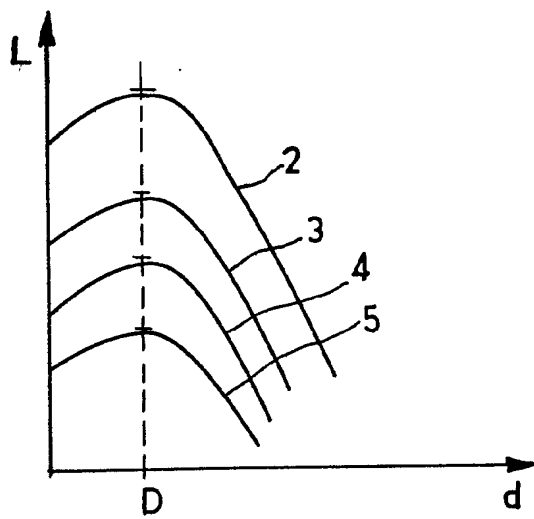


FIG.1

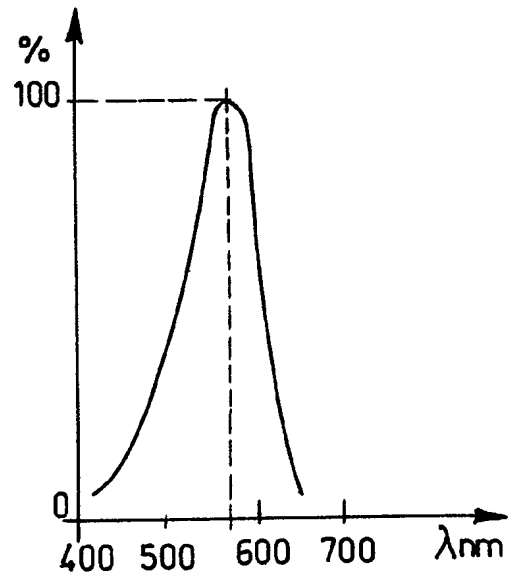


FIG.2

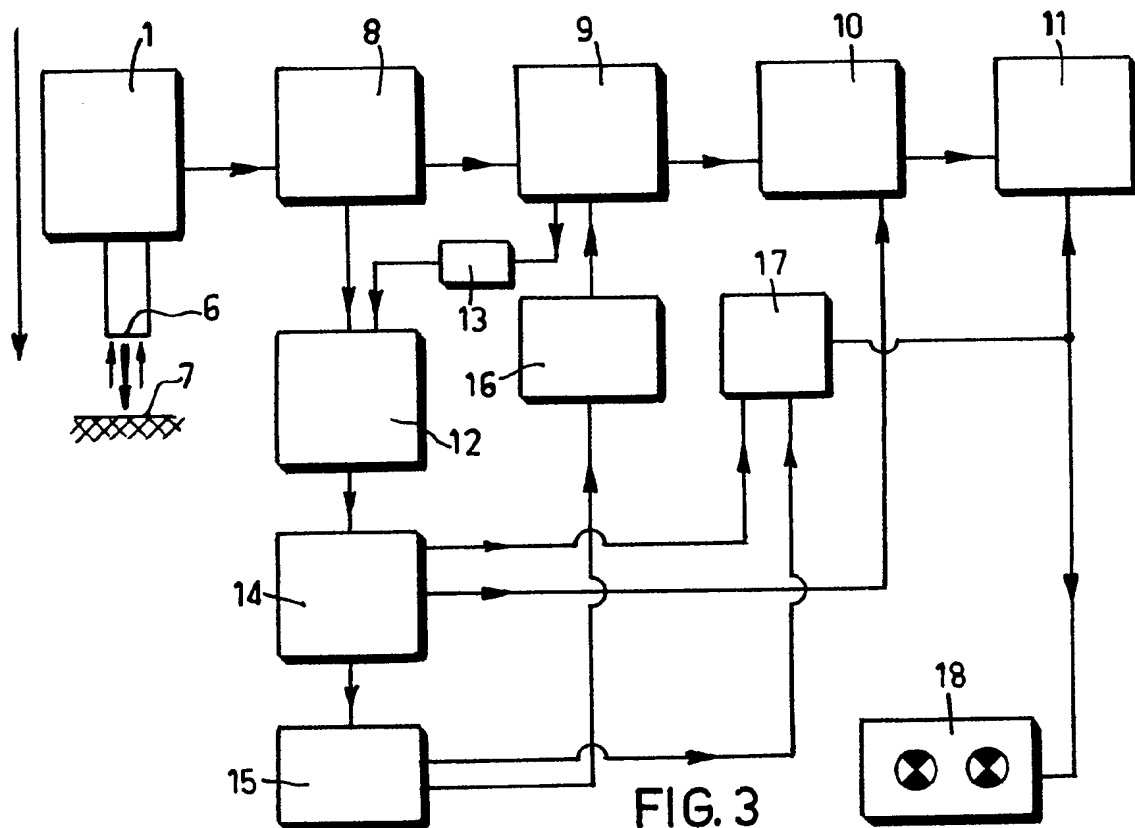


FIG.3

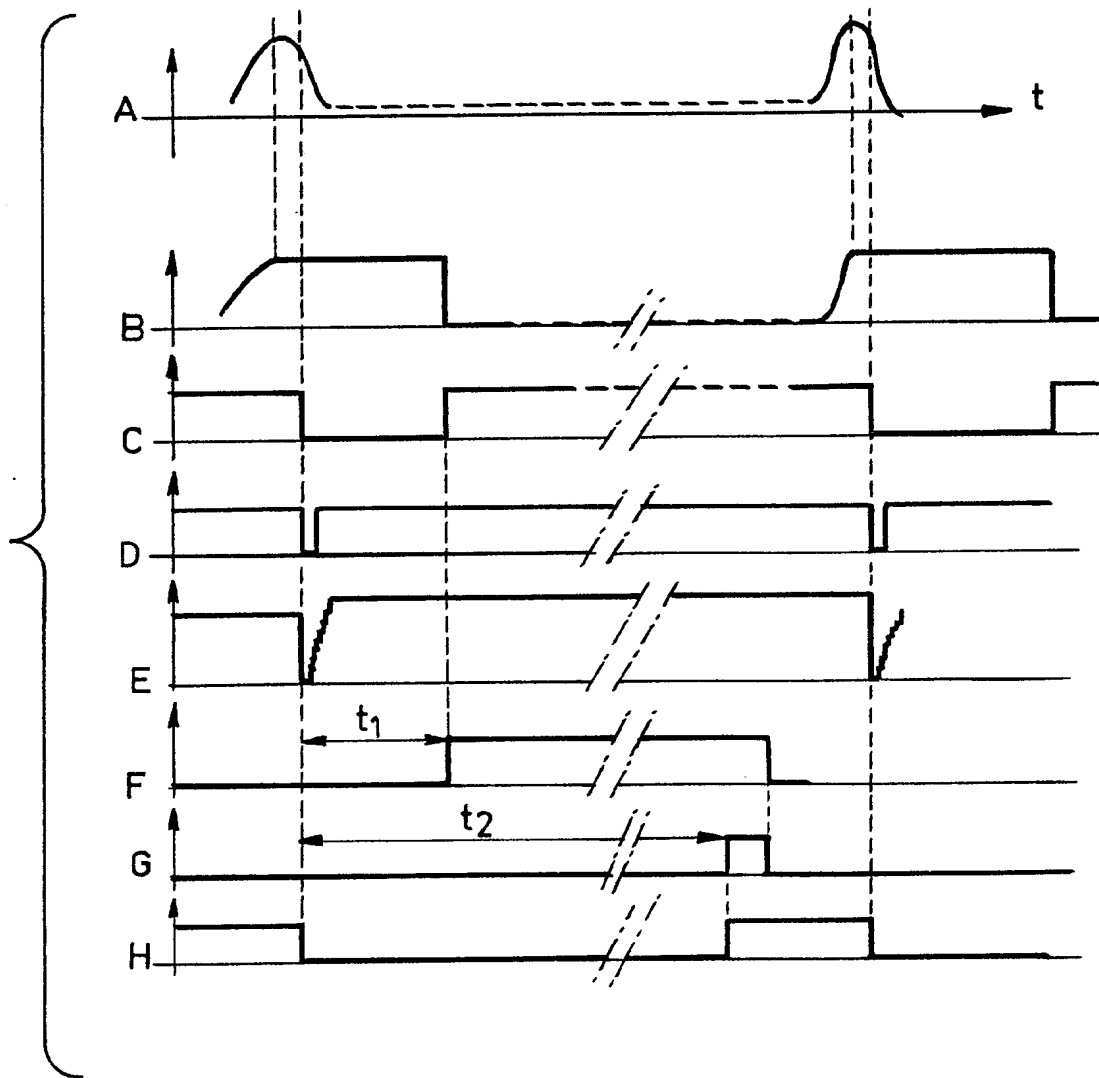


FIG. 4



## SPECIFICATION

### Process and apparatus for making a numerical determination of the colour, or of a colour change, of an object

The present invention relates to an apparatus and a process for carrying out a numerical determination of the colour, or of a colour change, of an object. More particularly the process and apparatus of the present invention do not require any contact with the object being investigated.

It is known that it is often desirable to allocate a numerical value to the colour, or the colour change of an object. Usually, the observation of an object by the human eye makes it possible to give qualitative information but this has two drawbacks. On the one hand, if the qualitative information is converted into quantitative data by an observer, the numerical value depends considerably on the judgement of the particular observer and may vary from one observer to another. Moreover, the human eye has difficulties in observation to allocate an indication corresponding strictly to the state of a restricted zone without taking into account the colour impression supplied by the surroundings of the observed zone; the surroundings are always taken into consideration so that the results of the qualitative observation of a zone depend largely on the contrasts supplied by the surrounding zones. This phenomenon is particularly evident when one is examining, for instance, the state of redness of human skin, particularly following solar radiation. The observation is affected not only by the intensity of the lighting but also by the background colour of the irradiated skin and by the extent of the contrast between the normal skin and the reddened skin.

It is, moreover, known that any apparatus permitting the numerical determination of an object's colour should be able to function without having to contact the object in the zone investigated. In fact, certain objects to be observed may be moving, or hot, or radioactive, and therefore they must not come into contact with the apparatus. Other objects may change their colour if they are subjected to pressure as is for instance, the case, with irradiated skin where contact pressure produces whitening due to closing of the capillaries. This colour change is also the case with liquid crystals which change colour according to the pressure to which they are subjected.

Now, in the present state of technology, a numerical determination of a colour is obtained by successively illuminating the object by luminous emissions corresponding to different wave lengths and measuring in each case the light returned by the object by way of reflection and diffusion towards a receiver.

This technique essentially requires the maintenance of a strictly determined distance between the measuring apparatus and the object subjected to observation, so in the case of soft materials it is necessary to bring the materials into contact with a glass plate or slide. It follows that a pressure which, even though of small magnitude, is not zero, is exerted on the objects to be observed and that this method is not suitable in the case of materials which change colour according to pressure or of those which are moving, hot, or radioactive. Moreover, in this known state of technology, the result of the measurement depends on the surrounding lighting and, in order to become independent thereof, it is not possible to use a pulsed source since in order to obtain a sufficient quantity of light reflected and diffused by the object it is necessary to use a powerful source. It will thus be seen that the present state of technology does not provide an apparatus which is capable of numerically recording a colour or a colour modification of an object in a simple and reproducible manner without contact with the said object.

The object of the present invention is to provide a process and an apparatus facilitating the numeral determination of a colour, or a colour change, of an object which do not require contact with the said object. Strictly speaking, the apparatus does not make it possible to obtain an absolute numerical measurement corresponding to a colour, but it makes it possible to make a numerical determination of a colour or a colour change which determination can be compared with determinations made by using other similar apparatus. With such an apparatus, it is for instance possible to study the effects of vasoconstrictors by examining the whitening of a human skin; it is also possible to study the extent of an erythema affecting a skin zone by comparing the measurement obtained on the said zone with a corresponding measurement obtained on a normal skin zone. One may, moreover, exert pressure on a reddened skin to close the capillaries and to whiten the skin zone concerned, then release the applied pressure and study the kinetics of the return of the skin to its original colour. The apparatus according to the invention thus finds a great number of applications and this all the more so, since its operation is extremely simple.

Accordingly one aspect of the present invention provides apparatus for making a numerical determination of the colour, or of a colour change, of an object, the apparatus comprising: a source of light to irradiate the object; a photo transducer to pick up the light returned by the object; optical fibre receiver means to direct the light returned by the object to the said photo transducer, the said optical fibre receiver means having an end displaceable substantially perpendicularly to the object being investigated to obtain the desired determination; optical fibre emitter

means to direct the emission of said light source to a said object being investigated; said optical fibre emitter means and optical fibre receiver means being fixed together for conjoint movement towards and away from a said object being investigated; a detection circuit for determining the value of the maximum of the signal supplied by the photo receiver during the displacement of the said end of the optical fibre receiver means; and a display unit responsive to said detection circuit for displaying information according to the determination made.

Another aspect of the invention provides a process for making a numerical determination of the colour, or of a change in colour, of an object comprising taking an apparatus according to the first aspect, moving said coaxial ends of said first and second optical fibre bundles towards said object while receiving the light from said light source returned from the said object, processing the output signal of said photo receiver using said detector circuit, and displaying the output of said detector circuit using said display unit.

The principle of the invention lies in sending a luminous emission on to the object to be investigated, receiving the light returned by the object and determining the maximum value of the reception as the receiving surface of the object subjected to the luminous emission is approached. When the emitting and receiving surfaces are the ends of optical fibre bundles, the intensity of the light retransmitted by the object generally passes through a maximum value if the two surfaces of the object are simultaneously brought near each other. The distance corresponding to the attainment of this maximum value only depends on the geometry of the receiver system and therefore if it is the said maximum value itself which is determined, the measurement of the retransmitted light is always effected at the same distance from the object. The result is thus independent of any constraint imposed by the apparatuses of present-day technology.

The measurement assembly may have a spectral sensitivity corresponding to the sensitivity of the human eye; it is possible to effect correlations between the measurements effected and direct visual observations. If the filter used allows a light to be emitted having a wave length corresponding to the object's colour, the object will return a maximum quantity of light to the receiver. On the other hand, the greater the difference of the object's colour from the medium wave length of the light emission used, the more the quantity of light returned to the receiver by the object will be reduced. It will thus be seen that the intensity of the maximum value of the output signal from the photo transducer essentially depends on the colour of the object for a luminous emission having any given spectral characteristics. If one examines, with the

same light emission, two differently coloured zones of the same object or the same zone of the object after its colour has been modified and if the results of the two measurements are compared, one obtains a numerical indication of the colour modification of the object which is practically independent of the light emission used.

In a preferred embodiment of the apparatus, the said first and second optical fibre bundles have their ends coaxial and in the same plane substantially parallel to the object, it being possible to cause the said ends to approach the object substantially perpendicularly to the object in order to effect the required determination; the receiver picks up from the object reflected light filtered through an optical filter whose wave lengths are distributed around a medium wave length approximating to the wave length corresponding to the object's normal unmodified colour; provision may also be made for the light emitter to comprise an optical filter emitting a light whose spectral distribution approximates to that corresponding to the sensitivity of the human eye; the signal processing detector circuit comprises a peak detector comprising an analogue memory; the peak detector is connected to the input of an analogue/digital and digital/analogue converter whose output feeds the display unit; the display unit comprises a volt meter; a signal proportional to the output signal of the peak detector (the proportionality coefficient being less than 1) is compared in a comparator with the output signal of the photo transducer and the comparator initiates, at the moment the two compared signals are equal, resetting to zero of the said converter as well as the start of a first timed period at the end of which, the peak detector is reset to zero and a second timed period is started, at the end of which, the display unit is reset to zero.

The apparatus according to the invention has the advantage of being extremely simple to handle since it suffices to bring the optical emitter-receiver fibre bundles near the object to be investigated until they are in contact with the object or in the immediate proximity of this contact if such contact must be avoided. In any case, whether contact with the object is established or not, the measurement is effected before the said contact takes place so that the measurement is not disturbed by any possible disturbing effect of the contact of the optical fibres on the object.

The result of the measurement is numerically displayed on a digital voltmeter which is automatically reset to zero after a certain display period so that it is possible to effect a great number of measurements in an extremely short time. Moreover, it should be observed that the measurement effected only concerns an extremely limited zone of the object investigated and that it is completely

independent of the colouration of the object's surrounding zones: thus one is no longer dependent on the ability of the human eye to take into account the colourimetric data of the

5 surroundings of the zone subjected to observation. The apparatus supplies a colour determination for a given filtering of the returned luminous emission but of course, the numerical value obtained is modified if the spectral characteristics of the light emission or of the  
10 filtering are changed. On the other hand, the results which can be obtained by the apparatus are much more independent of the luminous emission if a colour modification is studied, that is to say if one effects a measurement on a zone of the object and compares it with a similar measurement made on the same object with the same luminous emission, either at the same point or at a different  
15 point after the colour of the observed zone has been modified.

In the special case where the apparatus is used for an investigation of the skin, it is preferable to use an optical filter giving a  
25 maximum intensity in yellow and whose total range is in the visible spectrum. In these conditions, the maximum response of the apparatus is obtained by examining a yellow object and the examination of a normal skin allows approximately 70% to 80% of the maximum response to be obtained. If erythemas of the skin are studied, it will be seen that the redder the skin the lower the numerical value obtained, and for a pronounced  
30 erythema, the reception value of the sensor is approximately 10 to 20% of the maximum response of the said sensor.

In order that the present invention may more readily be understood, an embodiment represented on the accompanying drawing will now be described, by way of a purely illustrative and non-restrictive example. In these drawings:

*Figure 1* represents the curves giving luminous intensity  $L$  returned by the object (and picked up by the photo receiver) for a given  
45 luminous emission in relation to distance  $d$  between the object and the end of the optical fibres of the emitter-receiver assembly used in the apparatus according to the invention, each one of these curves corresponding to a different colour of the object subjected to examination;

*Figure 2* represents the distribution of the spectrum obtained by means of the optical filter which is interposed ahead of the photo receiver of the preferred embodiment of apparatus;

*Figure 3* is a block diagram of the electronic circuit processing the output signal of the photo receiver of the apparatus according to the invention; and

*Figure 4* represents the formation, with respect to time, of the signal at various points  
65 of the block diagram of Fig. 3.

Referring to the drawings, there will be seen the emitter-receiver unit 1 of the apparatus according to the invention. Unit 1 comprises a light bulb which emits a white light, and an optical filter whose spectral characteristics are represented by the curve of Fig. 2.

The luminous beam is sent into an emitter optical fibre bundle which constitutes at its end surface 6 the sheath of a second optical  
70 fibre bundle coaxial with the first. The two coaxial, optical fibre bundles have a common end surface 6, the second bundle serving as a receiver intended to receive the luminous flux returned by the object which is subjected to the incident flux originating from the emitter optical fibre bundle. The second optical fibre bundle or receiver bundle is connected to a photo transistor which constitutes the photo transducer of the apparatus according to the  
80 invention. The emitter-receiver unit 1 is not described in greater detail because it is marketed by the Company "SKAN-A-MATIC" of the United States of America under reference number "S 35203", with the optical filter.

In view of the geometry of the optical fibre bundles, the light emitted by the peripheral emitter fibre bundle and returned by the object only enters the optical receiver fibre bundle under certain angular pre-conditions so  
90 that the light intensity detected by the photo transistor which is connected to the receiver fibre bundle passes through a maximum when the common ends of the emitter and receiver fibre bundles are located at a distance  $D$  (Fig. 1) from the object being investigated.

Fig. 1 shows the shape of the curve indicating light intensity  $L$  determined by the photo receiver in relation to distance  $d$  from the front end surface 6 of the optical fibre  
100 bundles in relation to the object. Distance  $D$  corresponding to the maximum value of the light reception is always the same for a given emitter-receiver unit 1.

The different curves represented on Fig. 2 show the light intensities received by the photo transistor, according to the colour of the object which is presented in front of the end surface 6 of the emitter-receiver bundle assembly. If this object has a colour whose  
110 wave length corresponds to the maximum of the spectral distribution of the particular filter selected, the light intensity detected by the photo transistor is the maximum one which corresponds to curve 2 of Fig. 1. On the other hand, the more the object's colour differs from the dominant colour of the filter the lower is the light intensity detected by the photo transistor; curves 3, 4 and 5 show the light reception levels for orange, orange-red and red objects whilst curve 2 corresponds to a yellow object. As will be clear from the wave lengths indicated in Fig. 2, the filter is centred on yellow.

The values of the maxima of curves 2, 3, 4  
130 and 5 therefore constitute a determination of

the colour of the object which is presented opposite the end surface 6 of the coaxial optical fibre bundles. Of course, the numerical values corresponding to these maxima depend essentially on the nature of the filter which has been used for their determination. On the other hand, if a given object changes its colour and if the same apparatus is used to effect measurements both before and after the colour modification, comparison of the results of the two measurements will give a determination of the colour modification which colour modification determination depends to a far lesser degree on the nature of the light emission used.

To effect the measurement, it is sufficient to bring the end surface 6 of the coaxial optical fibres near to the object, either right up to contact with the object if there is nothing prohibiting contact or up to a proximity of a few millimetres if contact with the object must be avoided. In the course of this approach, the photo transistor output signal passes through a maximum at the moment when the end of the optical fibres is at a distance D from the object. As will be described in detail below, the apparatus allows the measurement to be effected at the precise moment when the distance d passes the distance value D.

This technique is particularly worthwhile if it is intended to study erythemas of the skin, because in that case it is possible to bring the end surfaces of the optical fibres right up to contact with the skin although this contact will cause the skin to whiten and will therefore modify the colour of the observed zone since the measurement is taken at a moment before the contact has been effected and when, therefore, the skin still retains its unmodified colour.

In Fig. 3, there has been shown the block diagram of the electronic circuit which allows the measurement to be obtained at the moment when end surface 6 of the optical fibre bundles is located at distance D from object 7 being investigated. The output signal of the photo transistor of the emitter-receiver unit 1 is sent to an amplifier 8 whose output is applied as input to a peak detector 9. In the conventional manner, the peak detector 9 comprises a capacitor having a sizable time constant, about 10 seconds for instance, since this capacitor only discharges very slowly.

The output signal of amplifier 8 is represented on line A of Fig. 4 for the part which corresponds to the passage of the photo transducer output through the maximum, i.e. at a moment when end surface 6 of the optical fibre bundle is at a distance D from object 7. The signal supplied at the output of peak detector 9 is represented on line B of Fig. 4.

This signal is directed to an analogue/digital and digital/analogue converter 10. When reset to zero, the converter 10 charges a memory at the frequency of its internal timer

and converts the memory content into an analogue output voltage and it compares the output voltage with the input voltage; the charging of the digital memory continues until the output voltage is equal to the input voltage; at this moment, converter 10 is blocked until it receives a reset pulse to cause it to reset to zero. The output voltage supplied by converter 10 is applied to a digital voltmeter 11 which constitutes the display unit.

The output from amplifier 8 is also applied to a comparator 12 whose second input receives the voltage corresponding to the output of peak detector 9 reduced by a proportionality coefficient of less than 1 derived from a divider bridge 13. In this embodiment, the proportionality coefficient selected is 0.75. The output of comparator 12 is thus a binary signal which is at the higher level while the output voltage of amplifier 8 is higher than that supplied by divider bridge 13 and which changes over to a lower level as soon as the opposite occurs.

This binary signal from comparator 12 is represented on line C of Fig. 4. The descending front of the signal on line C therefore indicates that the maximum of the output signal of the photo transistor of unit 1 has been passed and one may therefore charge the converter 10 with the value stored in peak detector 9. The use of a proportionality coefficient of 0.75 by virtue of the divider bridge 13, makes it possible to avoid any possible interference effects.

The output of comparator 12 controls a monostable device 14 whose output signal is represented in line D of Fig. 4. The output signal of the monostable device 14 is applied to the converter 10 and constitutes the reset signal, resetting the converter to zero to allow the digital memory of the converter to be charged at its internal timer frequency, which charge is produced in 150 nano-seconds at most. As explained above, when the output voltage of converter 10 is equal to the input voltage, converter 10 becomes blocked so that the display on voltmeter 11 remains constant, this display having changed during the charging time of converter 10. The output signal of converter 10 has been represented on line E of Fig. 4 but in this representation, the charging time of the converter has been greatly exaggerated to make it visible in the drawing.

The monostable device 14 releases a timing circuit 15 which supplies two timed periods.

The first timed period is determined by a signal represented on line F of Fig. 4. At a time  $t_1$  after the descending front of the pulse from the monostable device 14, the signal of the first timed period has a rising front which is directed to a transistor 16 arranged in parallel with the capacitor of peak detector 9. The first timed period signal thus produces the resetting to zero of the peak detector

output which does not affect the output of converter 10 since the converter has been blocked after completing its charging. The resetting to zero of the output of peak detector 9 also prompts change to the higher level of the output of comparator 12. In the example described, time  $t_1$  is approximately 20 ms.

The second timed period signal is represented on line G of Fig. 4. This signal has a rising front at time  $t_2$  after the descending front of the pulse produced by the monostable device 14. This rising front initiates by way of interface 17, the resetting to zero of the digital voltmeter 11, the output signal of interface 17 being represented on line H of Fig. 4. The second timed period signal constitutes a rectangular pulse and its descending front entails the resetting to zero of the signal relating to the first timed period. The signal supplied by interface 17 is reset to zero at the time of the descending front of the pulse supplied by monostable device 14. The signal supplied by interface 17 is therefore at its lower level during a timed period  $t_2$ , and  $t_2$  is chosen at the order of 20 seconds which allows the user of the apparatus to have the display of the measurement on digital voltmeter 11 at his disposal for 20 seconds. After these 20 seconds, the display of digital voltmeter 11 is reset to zero. An indicator device 18 is provided to indicate by one illuminated sign that the apparatus is in the measurement or reading off phase and by a different illuminated sign that the apparatus is on standby which makes it possible to effect a new measurement.

It will be seen that the apparatus which has just been described is simple to make so that its cost price is relatively limited. Moreover, it is very simple to use and the measurements effected can be taken very rapidly. The rapidity of these measurements makes it possible to study the kinetics of a change in colour which may for example extend over several minutes.

#### CLAIMS

1. Apparatus for making a numerical determination of the colour, or of a colour change, of an object, the apparatus comprising: a source of light to irradiate the object; a photo transducer to pick up the light returned by the object; optical fibre receiver means to direct the light returned by the object to the said photo transducer, the said optical fibre receiver means having an end displaceable substantially perpendicularly to the object being investigated to obtain the desired determination; optical fibre emitter means to direct the emission of said light source to said object being investigated; said optical fibre emitter means and optical fibre receiver means being fixed together for conjoint movement towards and away from a said object being investigated; a detection circuit for determining the

value of the maximum of the signal supplied by the photo receiver during the displacement of the said end of the optical fibre receiver means; and a display unit responsive to said detection circuit for displaying information according to the determination made.

2. Apparatus according to Claim 1, wherein said optical fibre emitter means and optical fibre receiver means comprise first and second optical fibre bundles having coaxial ends in the same plane substantially parallel to the object, the said ends being displaceable together substantially perpendicularly to the object to effect the desired determination.

3. Apparatus according to Claim 1 or 2, wherein the said photo transducer further comprises an optical filter.

4. Apparatus according to Claim 3, wherein said optical filter has a spectral distribution which approximates to that which corresponds to the sensitivity of the human eye.

5. Apparatus according to any one of Claims 1 to 4, wherein said detection circuit comprises a peak detector and an analogue memory.

6. Apparatus according to Claim 5, wherein said peak detector is connected to the input of an analogue/digital and digital/analogue converter whose output feeds said display unit.

7. Apparatus according to Claim 6, wherein said display unit comprises a voltmeter.

8. Apparatus according to Claim 7, wherein said voltmeter is a digital voltmeter.

9. Apparatus according to Claim 6, 7, or 8, including: means to obtain a signal proportional to the output signal of said peak detector, the proportionality coefficient being less than 1; and a comparator comparing the said proportional signal and the output signal of said photo transducer, wherein, as soon as the two compared signals are equal, said comparator initiates the resetting to zero of the converter as well as the start of a first timed period at the end of which there is produced both a resetting to zero of said peak detector and the commencement of a second timed period at the end of which said display unit is reset to zero.

10. Apparatus according to any one of Claims 1 to 9, which is usable for examining the skin, wherein the light emission is effected practically completely in the visible spectrum with a maximum in yellow.

11. Apparatus for making a numerical determination of the colour, or of a colour change, of an object, said apparatus being constructed and adapted to operate substantially as hereinbefore described with reference to the accompanying drawings.

12. A process for making a numerical determination of the colour, or of a change in colour, of an object, comprising taking an apparatus according to claim 1, moving said

coaxial ends of said first and second optical fibre bundles towards said object while receiving the light from said light source returned from the said object, processing the output signal of said photo receiver using said detector circuit, and displaying the output of said detector circuit using said display unit.

13. A process for making a numerical determination of the colour, or of a change in colour, of an object without contact with the object, comprising illuminating an object, moving a mobile light receiver means towards the illuminated object while picking up the light returned by said object, to cause the output signal of the light receiver means to rise up to a maximum value, and processing said maximum value of the output signal to derive a numerical value proportional to said maximum value.

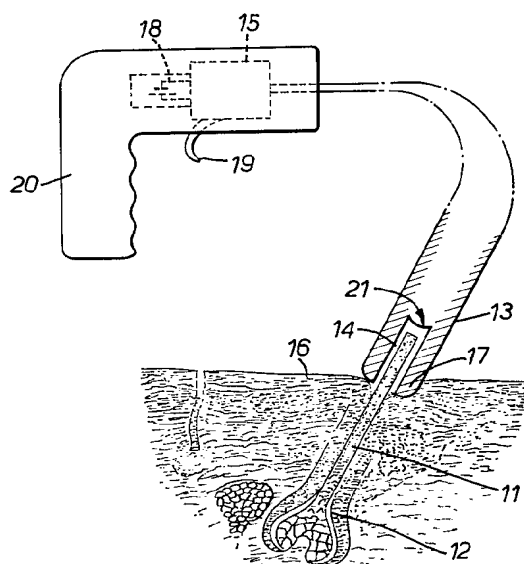
14. A process according to Claim 12 or 13, when carried out using an optical filter in the path of the said returned light picked up from the illuminated object, said optical filter having a medium wave length which approximates to the wave length corresponding to the normal unmodified colour of the object being investigated.

15. A process for making a numerical determination of the colour, or of a change in colour, of an object without contacting said object, such method being substantially as hereinbefore described with reference to the accompanying drawings.

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(54) **Depilation device**

(57) A depilation device includes a laser beam generator (15) embodied in a hand gun (20) with a trigger (19) enabling pulses of laser energy to be delivered along a flexible fibre optic probe (13) which has a bore in the end which can fit over a hair to be destroyed. At the end of the bore the optic is formed as a convex lens so that the pulses of energy are focused into the hair so that the hair and follicle can be destroyed without destroying surrounding tissue.



*Fig. 1.*

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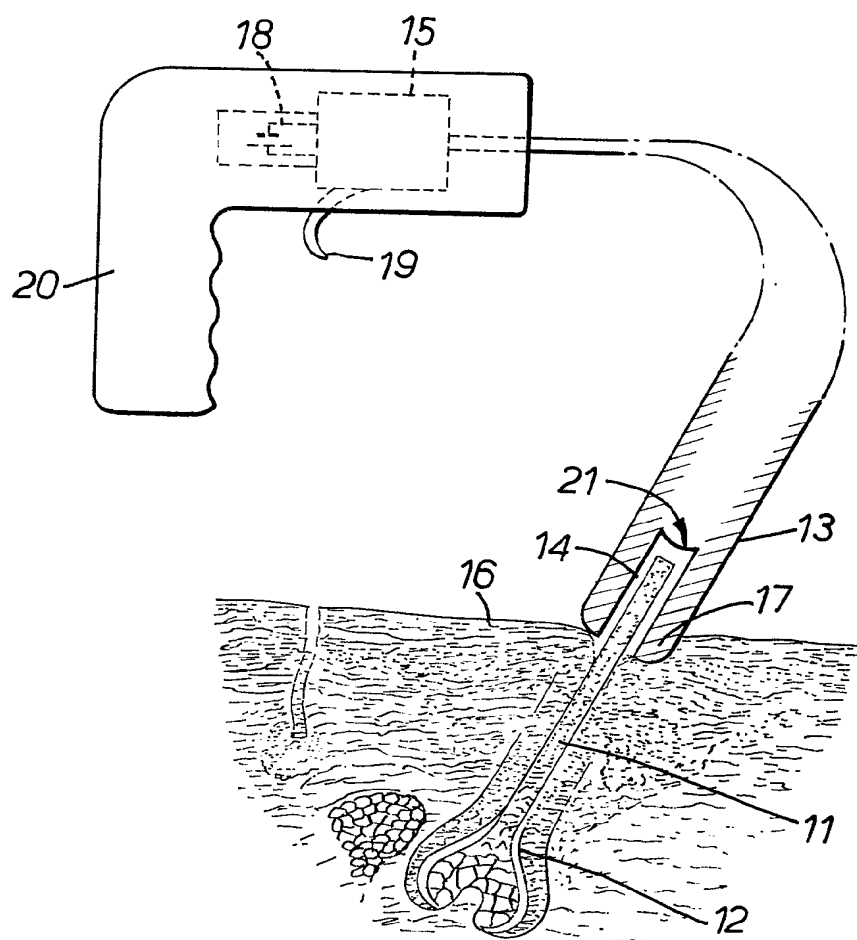


FIG. 1.



## SPECIFICATION

## Depilation device

5 This invention relates to a depilation device and one object is to provide such a device which enables the user quite easily and safely to destroy unwanted hairs without requiring expensive apparatus.

According to the present invention, a depilation  
10 device comprises a fibre optic probe with a bore at its tip to accommodate a hair; there is preferably a lens within the bore to focus energy in the probe into the hair.

By applying the tip of the probe over the hair a  
15 path is established for laser beam - or possibly other-energy to be applied as a pulse to the root of the hair or follicle thus preventing regrowth.

The bore may extend from the tip of the probe for a distance equal to the length of a cut-off hair, of  
20 perhaps two to three millimetres, and then the lens may be formed as a convex-ended closure to the bore so that it acts as a lens to focus the energy thus restricting the energy to flow within the hair to its follicle so as not to cause damage to surrounding  
25 tissues.

As human and mammalian hairs vary in thickness considerably, a selection of detachable probes will be necessary with different convergent lenses offering a range of focal lengths to accommodate the  
30 variation in depth of hair follicles. The external diameter of a probe could be 3 mm and internal diameters could range from 0.3 mm to 1 mm.

The invention includes the fibre optic probe connected to the output from a laser beam generator  
35 which is connected to a pulse forming circuit and a trigger with which to fire when the probe is in position and the hair is to be destroyed. Those components can conveniently be mounted in a hand gun equipped with a battery of commonly available  
40 type, to act as a power source for the laser beam generator.

This device has application in human dermatological therapy (including treatment of naevos and related conditions) cosmetic therapy and as veteri-  
45 nary treatments.

The invention may be carried into practice as illustrated in *Figure 1*.

In *Figure 1*, the hair 11 and its follicle 12 are to be destroyed and for that purpose a fibre optic probe 13  
50 is used. It has a central longitudinal bore 14 at its tip, about 2 to 3 mm long, of 0.5 mm - 1 mm internal diameter and approximately 3 mm external diameter.

A convex lens 21 is defined at the end of the bore.

At one end the probe 13 is connected to the  
55 discharge of a laser beam generator 15 so that light from the laser beam is conducted along the coaxial glass body of the probe to the lens 21. It is focused into the end of the hair and is conducted along the hair to the follicle where the energy is dissipated  
60 resulting in destruction of the follicle without damage to surrounding tissues.

The generator 15 is powered by a battery cell 18 connected through a pulse forming circuit to the laser beam generator 15 and when the trigger 19 is  
65 pressed a pulse of radiation is generated and

transmitted along the probe to be focused into the hair and its follicle in order to destroy them.

The components are conveniently housed in a pistol like body 20 housing the trigger 19.

70 It is anticipated that the energy necessary to destroy a hair (or a naevus or related dermatological conditions) might be approximately one joule so that a small battery can be effective for destroying a large number of hairs etc. The user merely applies the end  
75 of the probe to the hair (or the naevus etc) to be removed, and presses the trigger.

## CLAIMS

80 1. A depilation device comprising a fibre optic probe with a bore at its tip to accommodate a hair.

2. A depilation device as claimed in Claim 1 including a lens within the bore to focus energy in the probe into the hair.

85 3. A device as claimed in Claim 2 in which the lens is a convex lens formed at the end of the bore.

4. A device as claimed in any of the preceding claims in which the bore extends from the tip of the probe for a distance of 2-3 mm.

90 5. A device as claimed in any of the preceding claims in which the diameter of the bore is between 0.3 and 1 mm.

6. A device as claimed in any of the preceding claims in which the external diameter of the probe is  
95 about 3 mm.

7. A depilation device as claimed in any of the preceding claims in which the fibre optic probe is connected to the output from an energy generator connected to an energy pulse forming circuit and  
100 having a trigger with which the circuit can be fired.

8. A depilation device as claimed in any of the preceding claims embodied in a hand gun.

9. A depilation device constructed and arranged substantially as herein specifically described with  
105 reference to the accompanying drawing.

10. A method of destroying an unwanted hair by applying a pulse of energy into the end of the hair and hence into the hair follicle.

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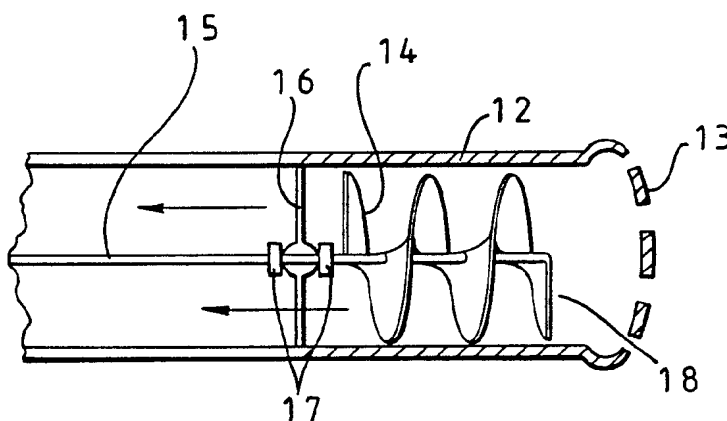
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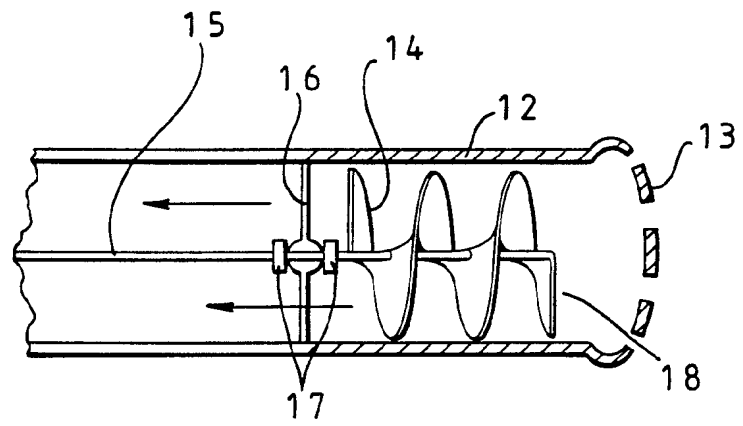
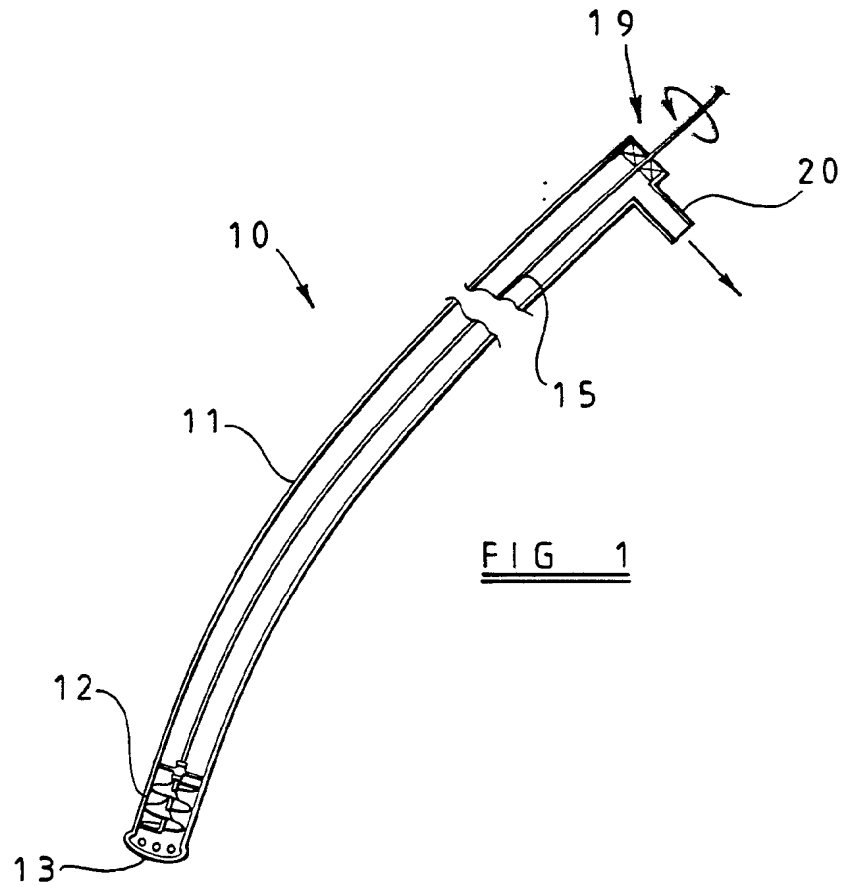
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(54) **Pump for pumping liquid**

(57) A pump for pumping liquid devised for medical or surgical use operates on an Archimedean screw principle and comprises a flexible plastics tube (11) having a flexible central drive cable or rod (15) stretching between its ends. An operative end (12) contains a Archimedean screw pump element (14) having a helix angle between 30° and 45° and centrally positioned by a spider (16). The operative end (12) has a filter mesh (13) and can be used for pumping blood, urine or other body fluids for example. The pump does not produce a vacuum and so avoids suction effect on surrounding tissue and the entrainment of large quantities of air.



**FIG 2**



Title: Pump for Pumping Liquid

This invention relates to a pump for pumping liquid.

It was particularly devised for medical and surgical use but may find application in other fields.

In medicine and surgery there is often a requirement to pump body liquids for example blood, urine or saliva. Conventional aspiration equipment uses a partial vacuum to suck fluid into a tube to a collection vessel.

There are several disadvantages to this method, especially in the medical and surgical context. Firstly, the suction is noisy. When the liquid is partially or completely drained, neighbouring tissue may be sucked against the tube by the vacuum, causing unnecessary damage to such tissue. Air is continuously drawn through a suction aspiration system. In situations where the aspired fluid is reintroduced to the patient, there is a risk of bacteria from the surrounding atmosphere being drawn into the liquid and concentrated by the action of the suction pump.

It is an object of the present invention to provide a pump for pumping liquid which does not rely on the creation of a partial vacuum.

According to the invention there is provided a pump comprising a tube, a helical pump element sized to be a close running fit within the tube, journal means for rotatably mounting the helical pump element at an operative end of the tube, elongate drive means for the helical pump element disposed within the tube and outlet means for liquid.

The tube may be flexible throughout its length except at the operative end.

The helix may have an angle of between  $30^{\circ}$  and  $45^{\circ}$ .

The drive means may comprise a Bowden cable or a rotary drive rod.

The outlet means may be laterally disposed at a position between the ends of the flexible tube. The operative end of the tube may have a filter.

The invention will now be described in more detail by way of example only with reference to the accompanying drawings in which:

Figure 1 shows a pump embodying the invention

Figure 2 is an enlarged detail view of the operative end of the pump.

Referring to the drawings, a pump generally indicated at 10 comprises an elongate flexible tube 11 which is made from plastics material. An operative end portion 12 of the pump comprises a rigid plastics tube, shown in more detail in Figure 2.

A grid or mesh 13 covers the operative end.

A helical pump element 14 is mounted concentrically with the operative end 12 of the tube. The pump element 14 has a helix angle of between  $30^{\circ}$  and  $45^{\circ}$  and is a close fit within the operative end 12 of the tube.

A drive rod or cable 15 extends generally centrally through

the tube 11 and is supported at the operative end by a spider 16. The drive cable or rod 15 has a pair of location abutments 17, one on each side of the spider, to prevent the helical pump element 14 from moving longitudinally in the tube.

In use, the operative end portion 18 of the pump is placed in an area to be drained and the cable 15 or drive rod is rotated at a variable speed by a suitable motor 19. The motor can be for example a battery operated DC motor or a compressed air drive unit. Liquid pumped on the Archimedean screw principle through the flexible tube 11 is discharged through a discharge opening 20.

The helical pump element 14 is a close fit within the rigid operative end portion 12 of the operative end. The rotation of the helical pump element can provide variable speed pumping of liquid in either direction but, because there is always equality of air pressure at either side of the blades of the helix, since they are not hermetically sealed, gases are not pumped by the apparatus. In other words, if the pump is being used to drain liquid from an area, when the liquid has been exhausted, there is no tendency for large quantities of air to be drawn through the pump. Where the liquid is blood for example, this may reduce air entrainment and hence contamination and deterioration of the blood, which is particularly advantageous if the blood is to be recirculated to the body.

The grid or mesh 13 prevents large solids entering the tube, for example blood clots or portions of tissue.

Since there is no vacuum created, there is no suction effect on surrounding tissues. No air pump is needed to operate the device. The rate of fluid removal is more easily adjustable

than in a conventional evacuation unit.

Peristaltic or roller pumps are frequently used in pumping blood for surgical procedures. However, these are of heavy construction and act by compressing a tube externally, at the risk of crushing the cell structure of the blood being pumped. They have the advantage of being bidirectional.

- However using the pump described, bidirectional pumping at variable rates can readily be achieved without substantial damage to the blood cells and without extensive air entrainment.

Such arrangements may also be used for bedside, peritoneal dialysis systems or continuous ambulatory peritoneal dialysis systems.

Bidirectional pumps of the type described could be provided in a miniaturised version capable of insertion into an artery or vein to facilitate blood withdrawal or infusion in haemodialysis.

Although the applications described above are principally in the field of medicine and surgery, the pump may be applicable in many other contexts. It could be arranged to be operated from a conventional domestic electric drill.

CLAIMS

1. A pump comprising a tube which is at least partly flexible, one end of the tube being an operative end, a helical pump element sized to be close running fit within the tube, journal means rotatably mounting the helical pump element at said operative end of the tube, elongate drive means for the helical pump element disposed within the tube, and outlet means spaced from said operative end of the tube for outlet of liquid pumped thereby.
2. A pump according to claim one wherein the tube is flexible throughout its entire length.
3. A tube according to claim 1 wherein said operative end only of the tube is rigid.
4. A pump according to any preceding claim wherein the helix has an angle of between 30° and 45°.
5. A pump according to any preceding claim wherein the drive means comprise a flexible Bowden cable.
6. A pump according to any one of claims 1-4 wherein the drive means comprise a rotary drive rod.
7. A pump according to any preceding claim wherein said outlet means are laterally disposed at a position between the ends of the tube.
8. A pump according to any preceding claim wherein said operative end of the tube has a filter.
9. A pump according to any preceding claim and made of biologically acceptable synthetic plastics material.
10. A pump substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.



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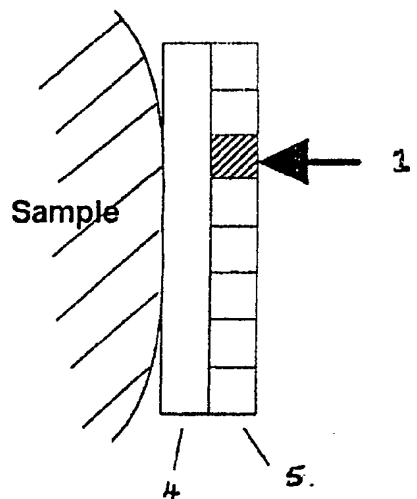
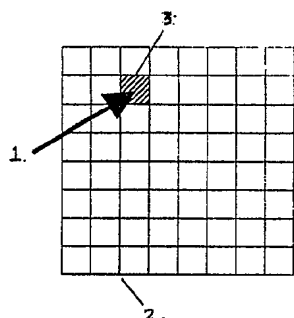
(58) Field of Search  
UK CL (Edition L ) **G1G GED GEEA GES GET , H4J JCX  
INT CL<sup>5</sup> G01N 29/24 , G10K 15/04 , H04R 17/00 23/00  
ONLINE DATABASES: WPI**

## (54) Optically controlled ultrasound array

(57) An optically controlled ultrasonic array comprises method and means of optically addressing and activating a slab of a suitable material which can be pixelated or continuous and which acts as a remotely controlled ultrasonic array. The slab is addressed and activated by a scanning optical beam or by an optical array, and replaces hard wired ultrasonic arrays reducing or eliminating transducer wiring and solid state switching. The scanned addressing and activation into acoustic oscillation of areas on the slab, effective pixel elements, is remote and faster than can be achieved by electronic switching of individual transducer elements on a conventional piezoelectric transducer array, eg. by optically switching electrical parts of the elements or by optically activating photo-sensitive cells which will generate the electrical signals necessary to energise the elements. The optical control can make use of a photo-thermal or photo-acoustic transduction process to generate acoustic waves. The system can be used for medical diagnosis or treatment as well as non-destructive testing or ultrasonic treatment, including plastic welding.

Diagram 4. Optically Controlled Ultrasound Array

Suggested embodiment:

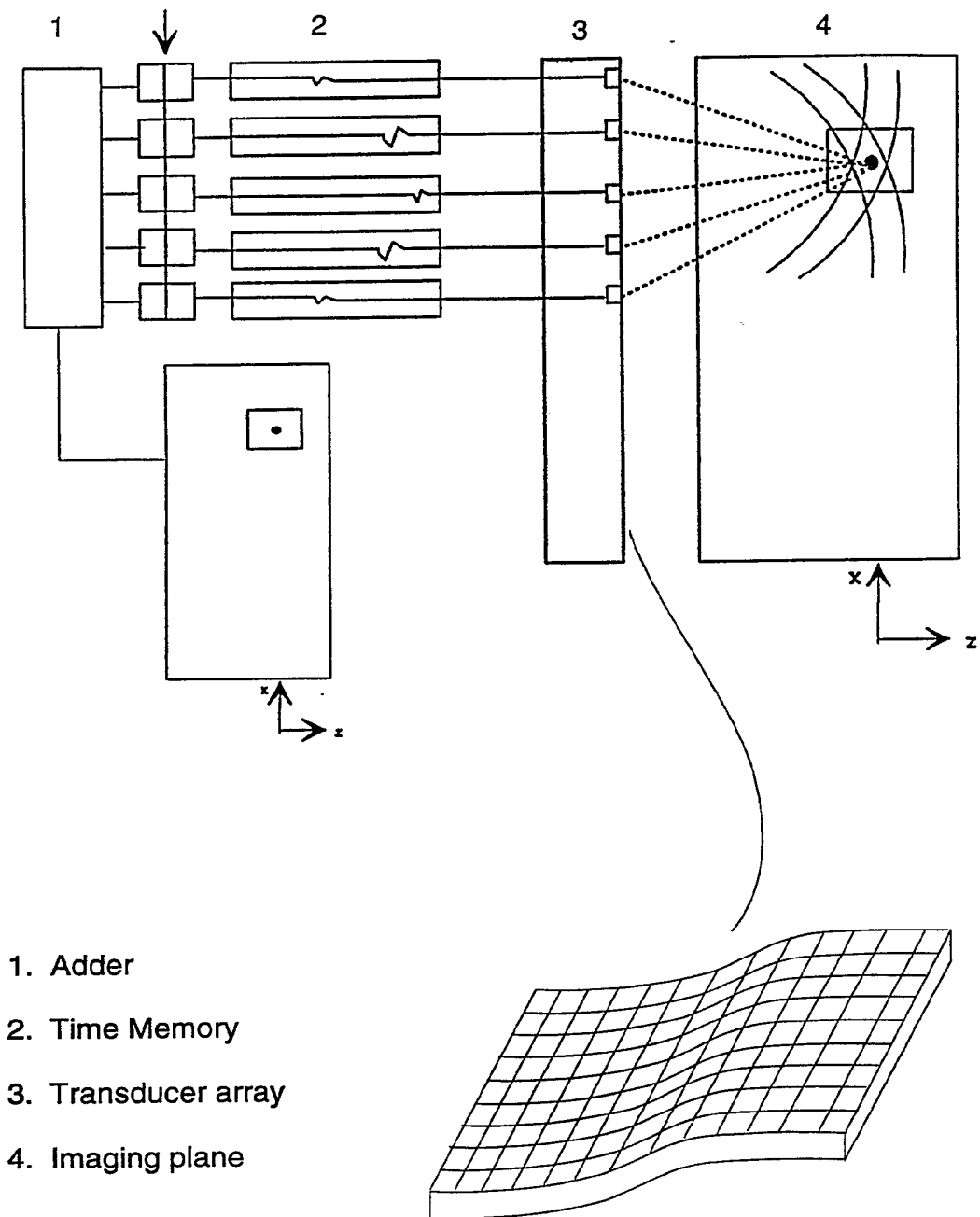


At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

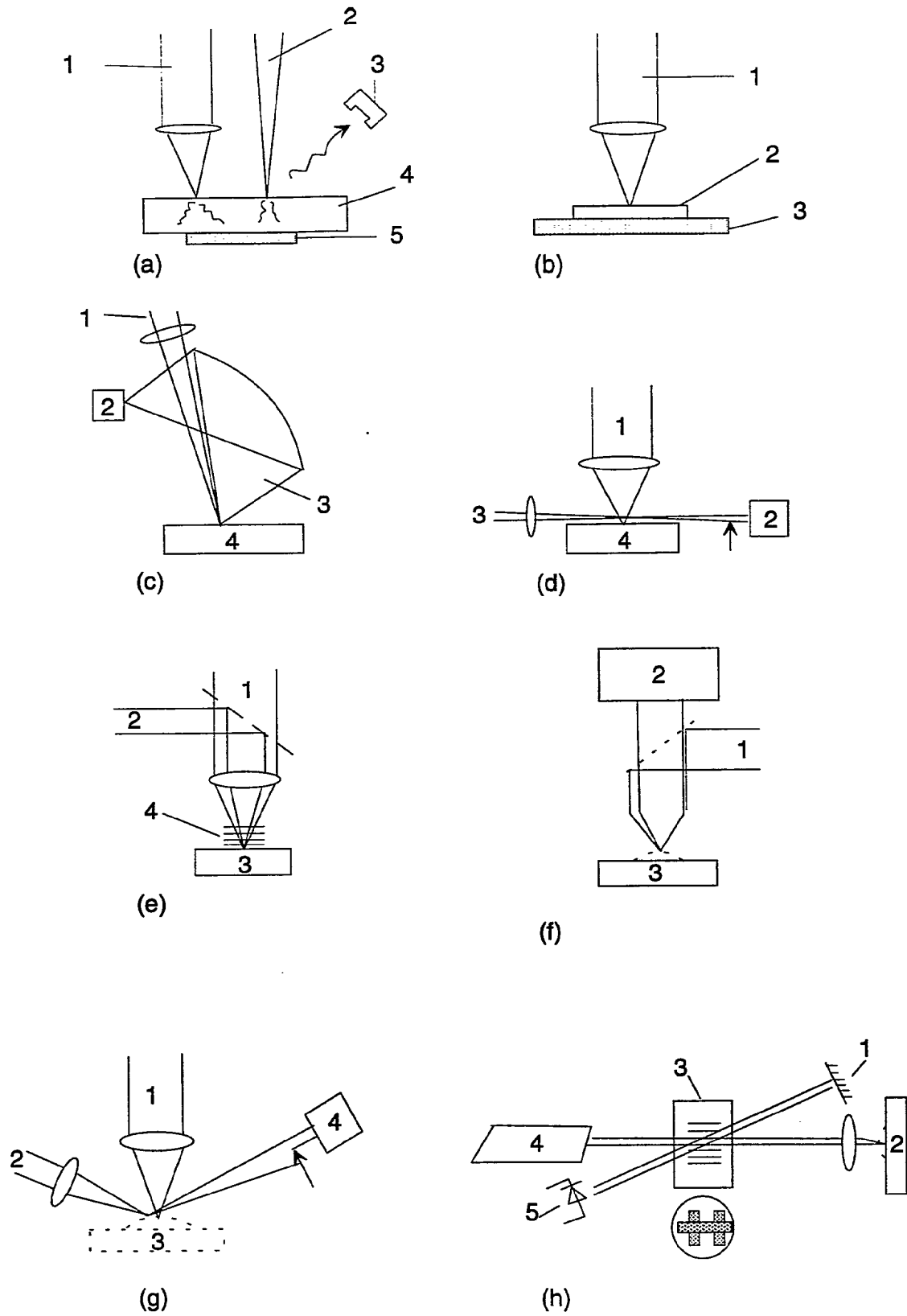
The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

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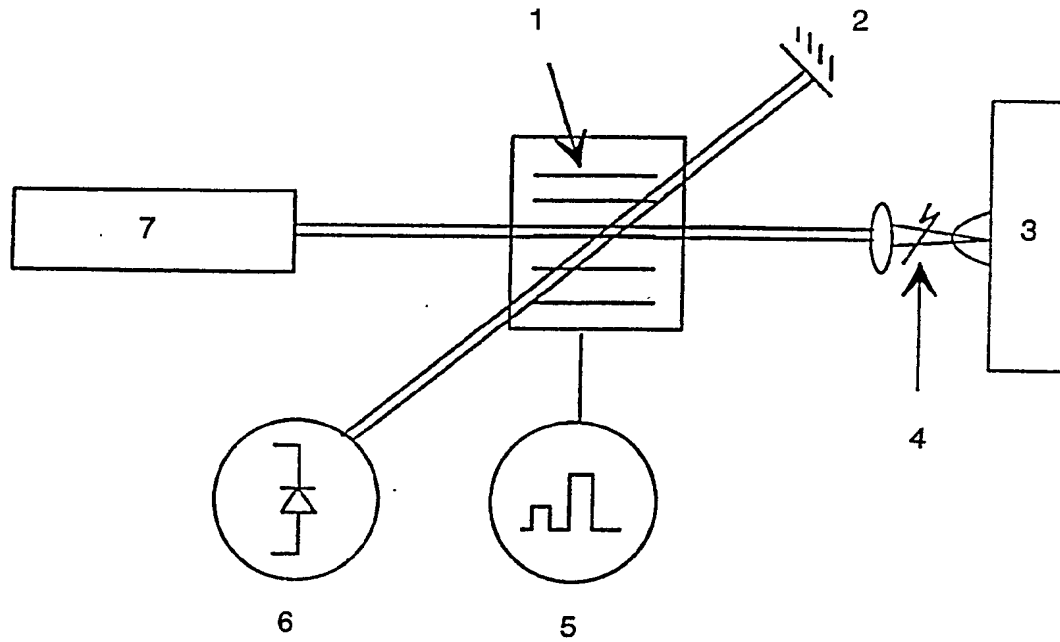
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**Diagram 1: Quasi-real-time synthetic aperture imaging (cf ref (4))**



**Diagram 2: Photo-thermal and photo-acoustic detection techniques**



**Diagram 3: Photo-displacement sensing using laser probe  
(modified Michelson interferometer)**

1. Adder
2. Time Memory
3. Transducer array
4. Imaging plane

**Diagram 1: Quasi-real-time synthetic aperture imaging (cf ref (4))**

## (a) Photoacoustic

1. pump laser
2. electron beam
3. microphone
4. sample
5. PZT

## (b) Pyroelectric Detection

1. pump laser
2. sample
3. pyroelectric detector

## (c) Photothermal

1. pump
2. detector
3. thermal I.R.

## (d) Mirage Effect

1. pump
2. detector
3. probe beam

## (e) Bragg Scattering

1. pump
2. probe beam
3. sample
4. acoustic wave in the gas

(f) Photo-displacement  
Interferometrical detection

1. pump
2. interferometer
3. sample

(g) Photo-displacement  
detection by Beam Deflection

1. pump
2. probe beam
3. sample
4. detector

## (h) Photo-Displacement with a single laser

1. mirror
2. sample
3. Bragg-cell
4. HeNe laser
5. photodetector

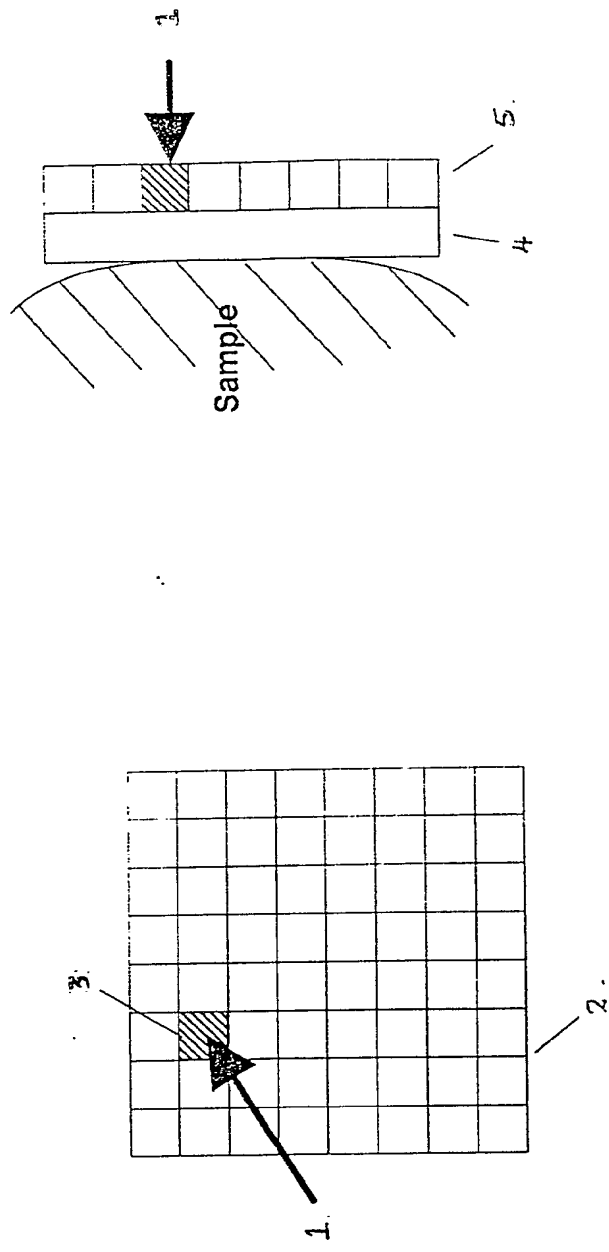
**Diagram 2: Photo-thermal and photo-acoustic detection techniques**

1. Bragg Cell
2. Mirror
3. Photoacoustic Transducer
4. Scanning Optics
5. Modulator
6. Detector
7. Laser

**Diagram 3: Photo-displacement sensing using laser probe  
(modified Michelson interferometer)**

Diagram 4. Optically Controlled Ultrasound Array

**Suggested embodiment:**





## OPTICALLY CONTROLLED ULTRASOUND ARRAY

### Background to the invention

This invention relates to ultrasonic imaging or detection systems used in a number of applications including medical diagnostic imaging and NDT. These systems normally employ a transducer to change electrical energy into acoustic vibrations. These transducers are normally made of a piezoelectric material such as PZT, composite materials containing PZT or similar transduction material, PVDF, crystal quartz, LiNbO<sub>3</sub>, ZnO each used depending on the frequency characteristics required. Transducers can also be made of magnetostrictive material.

The technology underpinning acoustic transducers is non-trivial and demanding applications in NDT and medical imaging constantly drive transducer technology improvements. Many of the imaging transducers are of a single element type which is then mechanically scanned. Applications for acoustic imaging range from a few KHz (sub-sea use) to several GHz (microscopy). One of the leading applications remains in medical imaging where frequencies in the few MHz range are used. Here, solid-state arrays are replacing mechanical scanners; single element transducers and annular arrays are being replaced by 1D and 2D arrays with dynamic focusing. Although, linear arrays with fine transducer pitch are in common use, the logistics of transducer manufacture and the considerable switching and processing has made a large, fine pitch 2D array as yet un-realistic.

The generation of acoustic waves through the interaction of light on a suitable material has many applications in imaging and defect detection, particularly in NDT. The phenomenon of Photo-acoustics was probably first used in practice by Alexander Graham Bell in 1880 ("On the production and reproduction of sound by light", Am. J. Sci., 20, pp 305-324). In 1881, Both Lord J.W. Strutt, 'Rayleigh' ("The photophone", Nature 23, p 274) and W.H. Preece ("On the conversion of radiant energy to sonorous vibrations", proc. Roy. Soc. 31, pp 506-520) provided some explanation of the phenomenon.

The generation of ultrasound by laser pulses was first suggested by 'Dick' R.M. White ("J. Appl. Phys. 34, p.3559) in 1963. A useful review appears in ( D.A. Hutchins, Phys. Ac., Vol. XVIII, W.P. Mason & R.N. Thurston, eds., Academic Press, San Diego, 1988, pp.21-123).

In general, the generation of elastic waves using a laser, is accompanied by:

- plasma formation (metals)
- dielectric breakdown
- electrostriction and local piezoelectricity
- vaporisation, ablation or thermoplastic behaviour
- thermoelastic effects
  - photothermal
  - photoacoustic

The first four effects are related to high intensities. With lower intensities, one is in the thermoelastic effect, which is suitable for NDT and imaging. The interaction of light with matter is often accompanied by the coupling of energy

into an acoustic mode, in turn generating heat due to the thermal conductivity, viscosity and relaxation mechanisms in the material.

The periodic heating of the surface by a modulated light source gives rise to a temperature cycling. This can be detected thermally (IR radiometry, pyroelectric detection), optically (diffraction effects in the gaseous coupling medium in the vicinity of the heated spot) or acoustically (microphone on solid, gaseous photoacoustic cell). In general, the heating is accompanied by a thermo-elastic effect and a thermo-acoustic effect (heated gas). Photothermal and photoacoustic effects are thus both there and it is up to the detection scheme to use one or the other as an imaging mechanism.

The thermal diffusion length, the depth of effective penetration and interaction, is proportional to the root of the thermal conductivity and inversely proportional to the modulation frequency and the sound velocity. The thermal effect is governed by a diffusion process and it can be detected optically in the close vicinity (within one diffusion length) of the source, both in the imaging medium (skin) and in the coupling medium (air). Further afield, the acoustic effect can be detected using a suitable transducer (e.g. a microphone); in the air, the effect of the acoustic field is attenuated and also suffers a large impedance mismatch between the solid and the gas.

#### PRIOR ART

Ultrasonic array transducers are in wide use. At frequencies applicable to medical imaging, these are normally made of PZT, PZT/epoxy matrices or PVDF. In general, PZT transducers with only a few dB insertion loss ( $20\log$  of the ratio between power in and power out) are possible, but bandwidths obtained are limited (5 to 20% typically). Using composites or PVDF, it is possible to obtain much wider bandwidths, even those approaching 100%, but inevitably, at the loss of efficiency (insertion losses of several tens of dB. PZT is a fired, compressed ceramic powder material, which is sturdy, but needs protection from moisture and extreme heat or large fields. Its acoustic impedance is c. 30MRayls, nearly two orders of magnitude higher than that of water. In order to improve the transmission of sound from the PZT element into water (or tissue, which has similar acoustic impedance) matching layers ( $1/4$  wavelength thick) of soft materials such as silicon rubbers are used.

The technology of the transducer manufacture is thus non-trivial and demanding. For large arrays, the logistics of switching adds yet another level of extreme difficulty. Each transducer must be switched according to the phase or timing requirement of the array. The responses must be comparable from transducer to transducer. Each element must be able to cope with both large transmission signals and small return signals, at times 100 dB smaller than the transmitted signal. This requirement for large dynamic range imposes demanding specifications on the switching and amplification electronics; added to this are the speed requirements. First, there must be sufficiently fast recovery after the large transmission signals. Then, there must be sufficient on/off (extinction) ratios in the switches. Finally, there must be sufficient isolation from element to element.

The ultrasonic array transducer and switching assembly are then connected to the transmitter/receiver electronics through a cable, often with as many wires as there

are elements, sometimes with some of these having been coded and compressed so that the cable is not impossibly fat.

## SUMMARY OF THE INVENTION

This invention provides an optical means of activating and addressing the ultrasonic transducer. In general, there are three ways in which one can achieve optical addressing and activation.

There are in essence three major aspects to this invention:

- Optically addressing and activating an ultrasonic transducer element by optically switching the electrical port of a conventional acoustic transducer element
- Optically activating a photo-sensitive cell which will generate the electrical signal necessary to energise a piezo-electric transducer
- Optically generating an acoustic signal by means of a photo-thermal/photo-acoustic transduction process through the absorption of the light energy. In this aspect of the invention, the acoustic wave can be generated either entirely by the light input, or by means of preconditioning the medium to need a limited light input to change its properties (eg matter phase change).

In all aspects of this invention, the optical addressing and activation will afford reduction or elimination of transducer wiring and solid-state multiplexing (switching); remote addressing; and fast scanning.

According to one aspect of the invention, acoustic waves are generated on the surface of a material to be tested (skin, metals, ceramics etc.) by an optical means of addressing pixel elements, which can be physically isolated or defined by the area of illumination. The pixel elements are designed to be light absorbing and generating an acoustic wave either directly or indirectly. In the direct method, the light absorbing pixel medium is designed for high photo-acoustic transduction efficiencies. In the indirect method, the light absorbing medium is designed for high efficiency photo-electric interaction.

## DETAILED DESCRIPTION OF THE INVENTION

According to one aspect of this invention, the pixelated transducer is made of a series of adjacent cells filled with a light absorbing dye. In another aspect of the invention, the pixelated transducer is made of a simple single layer or a complex multi-layer sandwich of soft and solid material designed for optimum transduction efficiency. In yet another aspect of the invention, the slab is not physically pixelated, but pixel elements are in effect defined by the size of the laser spot scanning over the surface. The scanning laser light spot may be a single or a series of simultaneous spots allowing serial or partially parallel phasing

of the elemental sources.

The scanning of harmonically or amplitude modulated light over the pixelated slab causes a logarithmic increase and an exponential decrease in surface temperature, in harmony to the modulation of the exciting laser light. Depending on the thermal properties of the scanned surface, there may or may not be a nett increase in surface temperature, a dc effect superimposed on the ac signal.

One aspect of this invention relies on the photo-acoustic generation of thermo-elastic waves as the basis for a new type of ultrasonic transducer array with optical phasing. According to our invention, the ultrasonic array transducer consists of a slab of pixelated photoacoustic elements. An amplitude or harmonically modulated light source scans the surface of the pixelated slab, causing the generation of an ultrasonic wave within the light absorbing medium contained within the slab. This medium may be a light absorbing dye or a metal with good photo-acoustic properties.

The process of photo-acoustic transduction generally has very small quantum efficiency. It is nevertheless possible to generate sufficient acoustic signals as the generation and dissipation of sufficiently high optical powers as excitation is not a major difficulty.

The proposed system consists of:

- A high power semiconductor laser source (Generics is already capable of producing 25 W into an optical fibre);
- An intensity modulation system (mechanical or Bragg-cell based);
- A novel multi-element photo-acoustic transducer array as proposed by Generics;
- A detection mechanism (photo-displacement detection directly on transducer elements or separate single-element piezoelectric detector).
- A digital imaging algorithm and the associated hardware (e.g. the Stanford DAISY system)

The proposed transducer is intended to provide acoustic energy at ultrasound frequencies and is thus a possible alternative to medical ultrasound arrays in some applications. The principle of operation of the transducer is photo-acoustic because the ultrasonic energy is thermally generated.

Photo-acoustic imaging is an established technique in NDT and much work has been carried out describing resolution and contrast mechanisms in microscopic imaging applications [6-10]. The art will be familiar to experts.

Thermal waves can be generated by any time-varying heat source. Light absorbed locally and characteristically by the illuminated portion of a sample is converted partly into thermal energy due to absorption. In harmony with the incident light intensity modulation frequency, a periodic heat flow results into the surrounding

region. This periodic heat flow (diffusion) is non-radiative within the sample because it is so highly damped that it reduces to  $1/e$  of its peak within one wavelength (the thermal diffusion length). The periodic heat flow also results in an acoustic wave which is not critically damped and thus propagates like a normal wave, interacting with and attenuated by sample properties over a much larger distance. In general, three processes contribute to the contrast:

- Local variation in the light energy absorption characteristics of the surface (reflection, absorption, de-excitation)
- Scattering of photo-acoustically generated thermal waves
- Scattering of photo-acoustically generated ultrasonic waves

High resolution photo-acoustic microscopy has depended mainly on the first of these effects, thus providing surface contrast. Interior imaging microscopy (ie photo-thermal microscopy) has depended largely on the second. The proposed medical ultrasound array will be based mainly on the third.

Typically, modulation frequencies in the 100 kHz to 10 MHz or more result in thermal wavelengths in metals of  $10 - 1 \mu\text{m}$  (some five times less in thermal insulators). However, the corresponding acoustic wavelengths are in the order of  $15 \text{ mm} - 150 \mu\text{m}$ . In photo-acoustic and photo-thermal imaging using low chopping frequencies, the acoustic wavelength is too coarse to be of interest and as a result, the acoustic wave is used as a carrier for finer thermal information. The Generics concept however makes use of the propagating acoustic wave in its interaction with the sample. In the case of medical imaging, it is intended typically to work at 2 to 5 MHz for useful resolutions.

The Generics concept thus boils down to using the photo-acoustic effect as a source of scannable acoustic energy in a new type of medical ultrasonic array.

#### FOCUSING AND SCANNING

Although it is appreciated that an ideal solution to fast imaging applications such as blood flow and certain specific cardiac cases is very important, we consider this to be a specialised area of flow analysis as opposed to imaging. It is, in our opinion, premature to address this particularly demanding specific case. During the discussion, we postulated 3D imaging and thus mainly spoke of a 2D array. It is indeed the expectation that the Generics concept will address 3D imaging applications; the approach will be to design first a linear array, followed by a phased array [1,2,11,12,13]. We thus describe the operation principle of a linear array as a basis of operation for a 2D array (3D imaging).

In a linear array, a single or a group of elements are fired to illuminate the sample in a direction normal to the face of the array. The scanning is performed by translating across the face of the array the firing sequence. In a phased array, a larger group of more closely packed transducers are fired simultaneously with appropriate phase (or timing) in order to produce a steerable focus.

There are a number of possible modes in which the proposed transducer may be scanned and a focus produced. We have postulated a system, which, on the

limit, relies on sequential triggering of a single transducer at a time. This will be the worse (slowest) case. We thus choose this case as an example to illustrate how the focusing and scanning may be achieved. Furthermore, the description is centred on a linear transducer capable of producing a B-scan image. Other more complex modalities are possible, but their working principle will be essentially based on the simpler steps to be described here.

In an ideal transducer both efficiency and bandwidth are high. The photo-acoustic transduction process is a lossy process and it is expected that efficiencies will be low and bandwidths fairly high. Efficiency will allow detectable return signals with sufficient dynamic range. Bandwidth will allow short pulse operation and thus both high inherent depth resolutions and faster possible scanning/processing rates.

We propose, -as a possible limiting case, a system using synthetic focusing of acoustic images. Such a system has been proposed and successfully demonstrated and implemented elsewhere, on a switched, hardwired, conventional acoustic transducer array [3,4]. The adaptation of the system to the proposed photo-acoustic system is best explained on diagram 1.

In transmit mode, the Bragg cell modulates the intensity of the laser beam at the required frequency, say 2 MHz. The modulated beam is then made to scan over the surface of the array (initially a linear array) so as to excite, with a pulse, a single element at a time (it may be possible to illuminate several elements simultaneously for phased array mode). Assuming a 30% bandwidth, the shortest possible pulse will be 1500 ns. Assuming an attenuation of 2 dB/cm in tissue, an imaging depth in B-scan mode of 5 cm will result in two-way attenuation of 20 dB at normal incidence. The wavelength in the tissue will be in the order of 750  $\mu\text{m}$  and in the transducer possibly in the order of 1.5 mm. A transducer pixel of this proportion will have a Fresnel distance of approximately 200  $\mu\text{m}$  at which little self-focusing occurs. The 3 cycle pulse emanating from the transducer will then travel into the depth, with any echo from 5 cm depth returning between 66 microseconds (at normal incidence) and c. 100 microseconds (for a 32 element array of say 8 cm length). If an image area of say 256x256 is required, the return signal can be quantised in .4 microsecond intervals, corresponding to a fraction of the 3 cycle pulse, well over the Nyquist limit. Allowing up to 100 microseconds delay per element, sequential triggering will translate to a frame rate of c. 3 ms or 300 Hz. With a 20 MHz clock rate, 10 samples per wavelength would be possible and up to 300 frames can be produced every second.

In receive mode, for every point of interest in the xz B-scan plane, a look-up delay table will give the appropriate pre-calculated delays per element channel. For each channel, a feature in time could have emanated from any point on a circle centred at the element and within the imaging area. By adding the time corrected signals from all the elements, as in a backprojection, the intersection between these circles, corresponding to the position of the feature is emphasised by the sum of the intensities. The received signal is upshifted by twice the modulation frequency as it passes through the Bragg cell for a second time before detection.

In a 2D array of say 32x32, one simple way of producing 3D images would be

to repeat the above operation for all elements, resulting in complete coverage of a volume approximately 8x8x5 cm in approximately 100 ms.

It is thus conceivable that real-time imaging will be possible even in 3D mode. At these rates, a jitter of 10 m/s from a feature in the tissue will cause an error of one two hundredth of a wavelength in the depth direction and around one wavelength from adjacent elements in the lateral direction.

We conclude that a quasi-real-time imaging system based on sequential aperture synthesis is likely to be possible. There is thus no need for the array to be either simultaneously illuminated nor for it to be illuminated necessarily within the phase delay between the closest and the farthest elements to points of interest in the imaging area.

#### DETECTION- PRINCIPLE

Whilst a number of detection schemes may be proposed (single piece piezoelectric detector, charge coupled delay devices etc.), it is likely that the signal levels will be too low for most of these. Signal levels are briefly discussed in the next section.

We consider first, detection based on a single piezoelectric element of wavelength proportions placed in the centre of the photo-acoustic array. It is shown in the next section that acoustic power levels c. 1mW can be expected for laser power input of 25 W, after a number of simplifying assumptions. In such a case the signal will be easily detectable and the detection bandwidth will not be a limiting factor. The implications of this on the scanning logistics must be considered. In transmit mode, the scanning is as described previously. In receive, however, the x,z position of the raster scan will correspond to a single distance, from the fired transducer to the x,z point and back to the receive transducer. This distance is unique for every fired transducer. Looking at the reflections due back from each fired transducer, the stored value for each delay could map to a number of possible positions. The aliasing thus produced is gradually corrected as the response due from other transducers are also added, emphasising true reflection features in common amongst the various transducers. This problem will be reduced if a phased array is employed, as the point of focus will be predefined during transmission.

The implications of the above during transmission scanning is that each line should be scanned fast enough for the longest delayed and shortest delayed returns to interact. For a 38 degree aperture half-angle (F 1.6) array to focus at one corner 5 cm deep, the shortest time is 66 microsecond and the longest 126 microsecond allowing 60 microsecond for scanning the elements sequentially, 17 kHz line rate (1.87 microsecond per element on a 32 element array). To focus at 1 cm depth along the axis of the transducer, this time difference is reduced to 14 microseconds. Thus the scanning speed and direction will define the focus uniquely in transmit. The digitised returns can be limited to a specific time window, expected to be the delay between the defined focus and the receive transducer. Thus during reconstruction, each x,z point in the raster will be associated to a specific memory location where the digitised return signal has been stored.

Naturally, it would be attractive to uphold the wireless nature of the transducer in receive mode also and to this end, we consider an alternative detection scheme using optical detection.

A number of photo-thermal and photo-acoustic schemes have been proposed in the literature and shown schematically in diagram 2, amongst which we propose a very highly sensitive surface displacement detection scheme known as photo-displacement microscopy [5], shown separately in diagram 3. This scheme is fairly well established and is otherwise known as the laser probe technique and has been demonstrated to produce sensitivities to  $10^{-4}$  angstrom displacements per Hz bandwidth.

To this end, a modified Michelson interferometer is used which incorporates an acoustically controlled Bragg cell. The Bragg cell will act as an active grating/splitter performing a number of tasks, amongst which are:

- Beam scanning;
- Intensity modulation of the incident beam;
- Isolation of incident and received beams in the frequency domain;
- Heterodyning of the signals for detection;
- The use of a single laser for surface heating and for displacement detection.

The photo-displacement signal is shifted to the second harmonic of the Bragg modulation frequency and easily detected in a bandwidth appropriate to the signal to noise levels achieved. It is this final detection bandwidth which is believed will ultimately define the frame rate.

Two possible modes of detection were described. It is concluded that although the detection scheme will be non-trivial, it will nevertheless be possible either to detect the signal using a piezoelectric element in the centre of the photo-acoustic array or to employ a photo-displacement sensing technique based on a modified Michelson interferometer capable of  $10^{-4}$  Angstrom/Hz depth resolution.

## SIGNAL LEVELS

A full analysis of overall signal to noise performance of the system will be required. We present here some preliminary considerations.

We assume a 25 W laser power over an area of 400 dimensions (This is a power density presently achieved by Generics designed semiconductor laser cluster).

Using one-dimensional theory, the peak temperature rise can be shown to be proportional to the peak laser power density and inversely proportional to the chopping frequency, density, specific heat capacity and the thermal diffusion length. For the 25 W laser power into fibre dimensions, this translates to a temperature rise of c. 13 degrees in water (.2 in a metal) per cycle. This corresponds to a deflection in the order of  $10^{-7}$  m on the surface of the heated



spot. Based on further assumptions yet to be verified, we calculate strains of  $10^{-4}$ , translating to an acoustic power output in the order of one Watt. Upon return from say 5 cm within tissue, this power will be reduced by some 30 dB, resulting in an acoustic power of 1 mW, c. 0 dBm, which is easily detectable acoustically from a single transducer.

These calculations and the assumptions taken are for illustrative purposes only and it is not suggested that a full 25 W laser will be used, nor that signal levels detected will be purely based on the above assumptions.

Based on the assumptions taken, it is concluded that adequate signal levels may be produced.

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- Diagram 1. Quasi-real-time sequential synthetic aperture imaging (cf ref. [4])
- Diagram 2. Photo-thermal and photo-acoustic detection techniques
- Diagram 3. Photo-displacement sensing using laser probe (modified Michelson interferometer)
- Diagram 4. Optically controlled ultrasound array

## Optically Controlled Ultrasound Array

### Claims

- 1 An ultrasonic or acoustic transducer element or array which is addressed and activated by optical means.
- 2 An ultrasonic or acoustic transducer element or array which is addressed and/or activated remotely.
- 3 A wireless ultrasonic or acoustic element or array.
- 4 A method of remotely generating or controlling acoustic or ultrasonic signals for the purpose of medical diagnosis or treatment or industrial non-destructive testing or acoustic treatment such as welding.
- 5 A means of generating acoustic or ultrasonic signals remotely by using a slab of pixelated or continuous material that is addressed by a scanning optical beam or an optical array.
- 6 The element or array of claim 1 where the electrical port of a conventional acoustic transducer element is optically switched.
- 7 The element or array of claim 1 where the optical addressing energises a piezo-electric transducer element or array through use of photo-sensitive cells.
- 8 The element or array of claim 1 where the acoustic signal is generated through a photo-thermal or photo-acoustic transduction process.
- 9 An acoustic or ultrasonic transducer element or array, where the scanning of the array is achieved through optically addressing the surface of the array directly, the surface being pixelated or continuous.

-13-

**Patents Act 1977**  
**Examiner's report to the Comptroller under**  
**Section 17 (The Search Report)**

Application number

GB 9205577.1

**Relevant Technical fields**

- (i) UK CI (Edition L ) G1G (GED, GEEA, GET, GES);  
H4J (JCX)
- (ii) Int CI (Edition 5 ) G01N (29/24); G10K (15/04);  
H04R (17/00, 23/00)

**Search Examiner**

D L SUMMERHAYES

**Databases (see over)**

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

**Date of Search**

8 JULY 1993

Documents considered relevant following a search in respect of claims

1-9

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB 1583057 (IBM)	1-4
X	US 4512197 (GUTFELD)	1-5, 9
X	US 4469977 (QUINN)	1-4
X	US 4269067 (TYNAN)	1-4
X	IBM Technical Disclosure Bulletin, Vol 21, Number 8, January 1979, R J von Gutfeld and S S Wang, "Laser Generated Acoustic Fan Beam Ultrasound Tomograph System" pages 3441-3442	1-4

### Categories of documents

**X:** Document indicating lack of novelty or of inventive step.

**Y:** Document indicating lack of inventive step if combined with one or more other documents of the same category.

**A:** Document indicating technological background and/or state of the art.

**P:** Document published on or after the declared priority date but before the filing date of the present application.

**E:** Patent document published on or after, but with priority date earlier than, the filing date of the present application.

**&:** Member of the same patent family, corresponding document.

**Databases:** The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

# (12) UK Patent Application (19) GB (11) 2 356 570 (13) A

(43) Date of A Publication 30.05.2001

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(51) INT CL<sup>7</sup>  
**A61N 5/06**

(52) UK CL (Edition S )  
**A5R REHR**

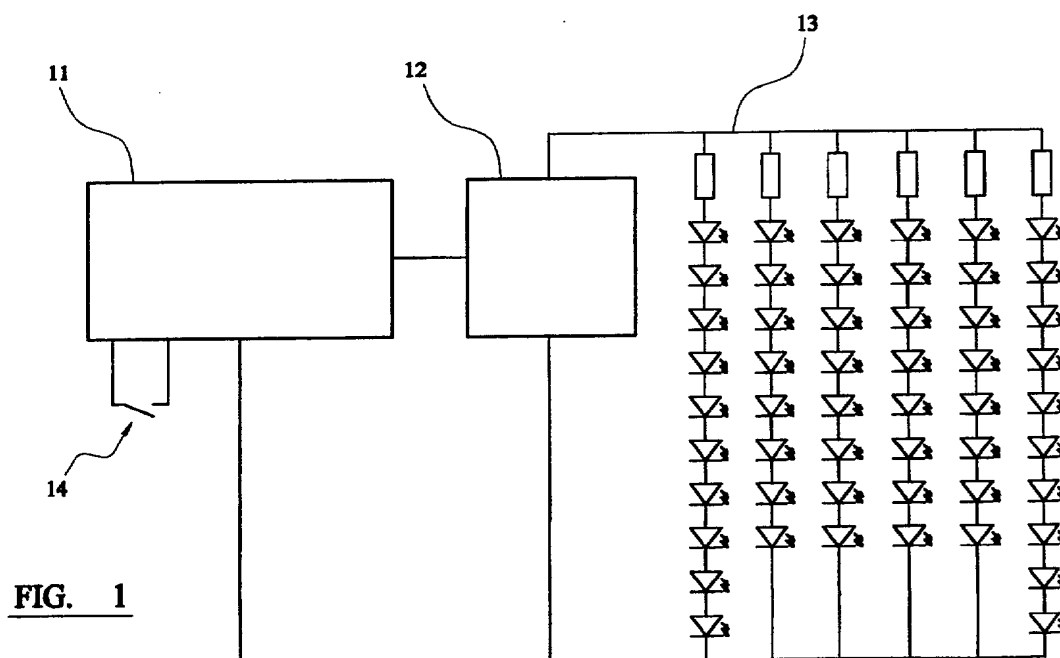
(56) Documents Cited  
**EP 0884066 A2 WO 96/14899 A1 DE 004440112 A**  
**DE 004026327 A FR 002752739 A US 5549660 A**

(58) Field of Search  
UK CL (Edition R ) **A5R REHR**  
INT CL<sup>5</sup> **A61N 5/06 5/08**  
**ONLINE:WPI,EPODOC,JAPIO**

(54) Abstract Title  
**Acne treating apparatus based on the emission of light in three different ranges of wavelength**

(57) An acne treating apparatus comprising light emitting means (13) which, in use, emit light onto an area of skin to be treated wherein the light emitting means is adapted to emit light at three different wavelengths, the first wavelength of light selected from the range of 365 to 465 nm, the second wavelength of light selected from the range of 585 to 645 nm and the third wavelength of light selected from the range 646 to 710 nm.

The light emitting means are preferably super luminous light emitting diodes (SLEDs) with an output of up to 50mW per cm<sup>2</sup>. They may emit continuous or pulsed light. The operation of the apparatus is preferably controlled by a microprocessor (11).



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The print reflects an assignment of the application under the provisions of Section 30 of the Patents Act 1977.

GB 2 356 570 A

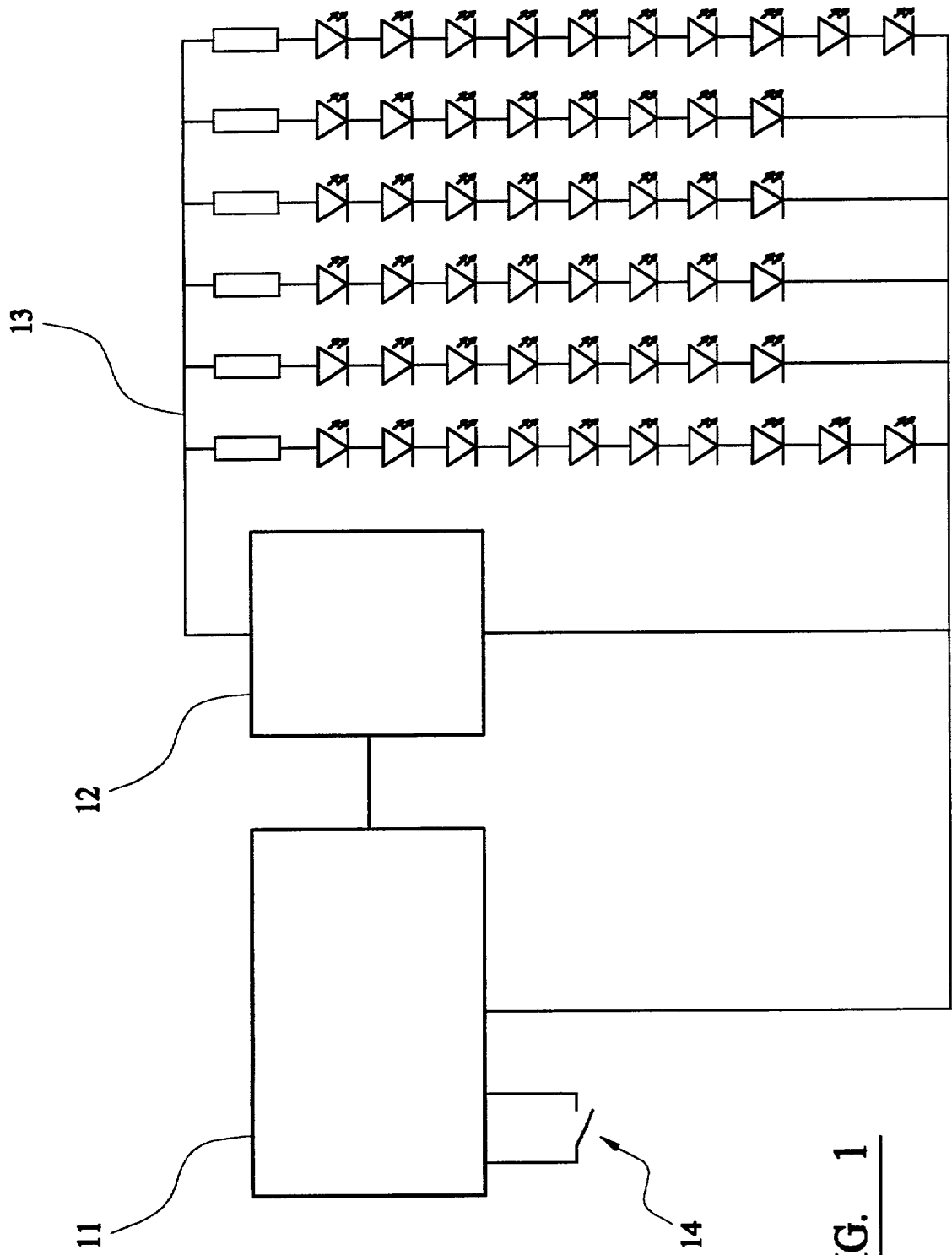


FIG. 1



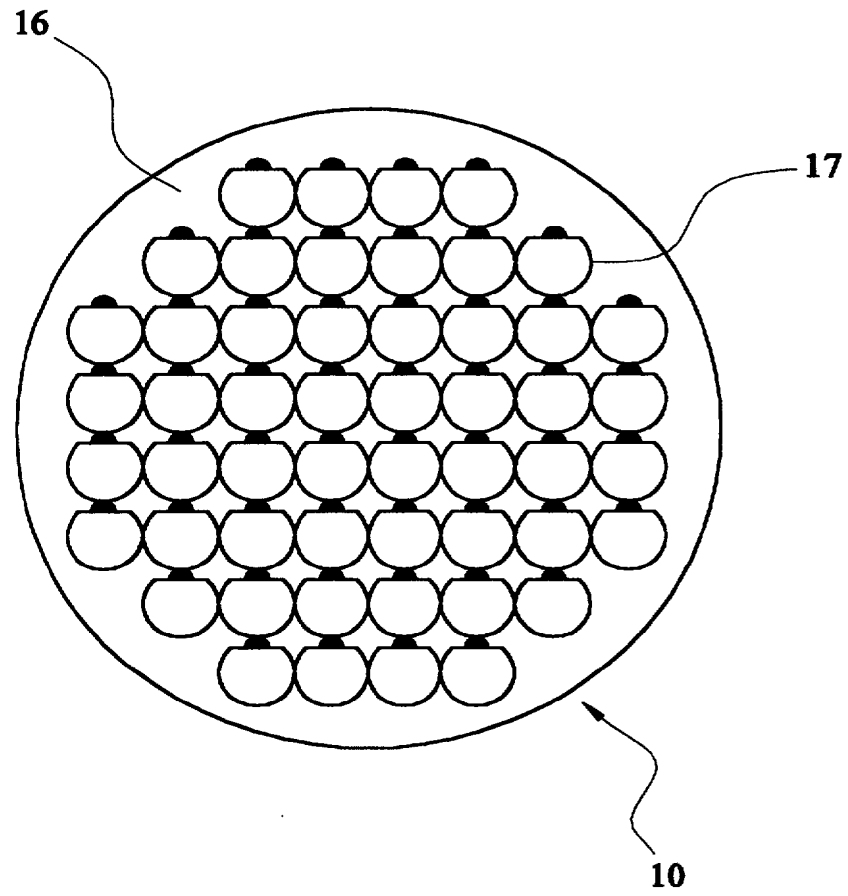


FIG. 2

## AN APPARATUS FOR THE TREATMENT OF A SKIN COMPLAINT

The present invention relates to an apparatus for the treatment of a skin complaint. More particularly, the present invention relates to an apparatus for the treatment of acne.

*Propionibacterium acnes* (*P.acnes*) are normal inhabitants of the human skin in particular, the pilosebaceous ducts. Increased amounts of *P.acnes* have been observed to be present in acne sufferers.

Research has established that *P.acnes* is microaerophilic, that is, it can only tolerate small amounts of oxygen, and that *P.acnes* use porphyrins in their respiratory system.

When subjected to certain wavelengths of light, it has been observed that porphyrins become excited and produce oxygen. In this connection, we have established that by triggering the excitation of porphyrins in this manner, it is possible to kill *P.acnes* and hence, treat acne.

According to the present invention there is provided an acne treating apparatus comprising light emitting means which, in use, emit light onto an area of skin to be treated wherein the light emitting means is adapted to emit light at three different wavelengths, the first wavelength of light selected from the range of 365 to 465 nm, the second wavelength of light selected from the range of 585 to 645 nm and the third wavelength of light selected from the range 646 to 710 nm.

In a preferred embodiment, the first wavelength of light emitted by the light emitting means is 415 or 440 nm, the second wavelength of light is 635nm and the third wavelength of light is 660nm. Research has shown that an apparatus emitting light at the aforementioned wavelengths provides good results.

In a preferred embodiment, the light emitting means are super luminous light emitting diodes (SLEDs). The advantage of using SLEDs is that they are capable of providing the required power intensity of light necessary to kill *P.acnes* in sufficient numbers to effect the pathogenesis of acne. Further preferably, the SLEDs are arranged in a cluster on a face of the apparatus in accordance with the present invention. Preferably, the cluster includes 16 SLEDs emitting light having a wavelength selected from the range of 365 nm to 465 nm, preferably 415 or 440 nm, 18 SLEDs emitting light having a wavelength selected from the range of 585 to 645 nm, preferably 635 nm, and 18 SLEDs emitting light having a wavelength selected from the range of 646 to 710 nm, preferably 660 nm. However, it is to be understood that the light emitted by an apparatus in accordance with the present invention can originate from any light emitting source, for example, via fibre optics.

Further preferably, the light emitting means can irradiate up to 50cm<sup>2</sup>, preferably 24cm<sup>2</sup>, of skin at any one time.

Further preferably, the light emitting means has an output of up to 50 mW per cm<sup>2</sup>, preferably 6mW per cm<sup>2</sup>.

Further preferably, the light emitting means can emit pulsed light. In this connection, research has established that all cells have energy intensity, wavelength and frequency windows. That is, specific values of these parameters can be used to increase cell permeability, as well as activate various forms of cellular activity, for example, synthesis, secretion and

intracellular communication. During our research, we have observed that the various forms of cellular activity mentioned above are increased when such cells are irradiated by specific frequencies of pulsed or modulated light. Additionally, we have observed that pulsed light can trigger the release of particular wound mediators, which accelerate tissue repair.

Further preferably, the light emitting means can emit continuous and pulsed light sequentially. The advantage of having an apparatus which can firstly apply continuous light and then pulsed light, is that exposure of the skin to continuous light will firstly kill the *P.acnes* and subsequent exposure of the skin to pulsed light, will additionally facilitate healing of the skin tissue.

Further preferably, the pulsed or modulated light emitted from the light emitting means has a frequency of 18Hz. We have observed that this frequency gives best results.

Further preferably, the apparatus in accordance with the present invention comprises control means for controlling the duration of light being emitted from the light emitting means and/or for switching between the emission of continuous light and pulsed light. This has the advantage in that the apparatus controls the duration of light and type of light being emitted and therefore, is less susceptible to human error. Further preferably, the control means causes the light emitting means to emit continuous light for a period of up to 40 minutes and/or pulsed light for a period of up to 40 minutes. Preferably, the control means causes the acne apparatus in accordance with the present invention to emit continuous light and then pulsed light sequentially. Further preferably, the control means causes the light emitting means to emit continuous light for a period of 5 minutes and then pulsed light for a period of 5 minutes.

Further preferably, the apparatus in accordance with the present invention is hand-held. This has the advantage in that the apparatus can be used to precisely direct the emitted light onto areas of the skin that are particularly infected with acne.

One embodiment of the present invention will now be described by way of example and with reference to the accompanying drawings in which:

Fig. 1 is a schematic diagram of acne treating apparatus in accordance with the present invention; and

Fig. 2 is a front view of the light emitting face of an apparatus in accordance with the present invention.

As illustrated in Fig. 1, an acne treating apparatus 10 in accordance with the present invention includes a microprocessor 11 that controls the duration and type of light being emitted by the apparatus 10 coupled to a power switching 12 and chains of super luminous light emitting diodes 13. Preferably, each chain of SLEDs include three different wavelengths and are ballasted to control the current therethrough. Additionally, the microprocessor has a start button 14 which when pressed, results in the activation of the acne treating apparatus 10.

As illustrated in Fig. 2, the apparatus 10, comprises a number of super luminous light emitting diodes 17 on the face 16 thereof. In the illustrated embodiment, 16 of the SLEDs located on the base 16 emit light having a wavelength of 415nm, 18 SLEDs emit light having a wavelength of 635 nm and 18 SLEDs emit light having a wavelength of 660 nm.

In a further aspect of the present invention there is provided a method of treating acne by exposing an area of skin to be treated to three wavelengths of light, the first wavelength of light selected from the range of 365 to 465 nm, the second wavelength of light selected from the range of 585

to 645 nm and the third wavelength of light selected from the range of 646 to 710 nm.

Preferably, the first wavelength of light has a wavelength of 415 or 440 nm, the second wavelength of light has a wavelength of 635 nm and the third wavelength of light has a wavelength of 660 nm.

Further preferably, the light is pulsed light. Preferably pulsed at a frequency of 18Hz.

Further preferably, the area of skin to be treated is treated with continuous light for up to 40 minutes and/or pulsed light for a period of up to 40 minutes.

Preferably, the area of skin to be treated is treated with continuous light and then pulsed light. Preferably, the area of skin to be treated is treated with continuous light for 5 minutes and then pulsed light for 5 minutes.

## CLAIMS

1. An acne treating apparatus comprising light emitting means which, in use, emit light onto an area of skin to be treated wherein the light emitting means is adapted to emit light at three different wavelengths, the first wavelength of light selected from the range of 365 to 465 nm, the second wavelength of light selected from the range of 585 to 645 nm and the third wavelength of light selected from the range 646 to 710 nm.
2. An apparatus as claimed in claim 1, wherein the first wavelength of light emitted by the light emitting means is 415 nm, the second wavelength of light emitted by the light emitting means is 635 nm and the third wavelength of light emitted by the light emitting means is 660 nm.
3. An apparatus as claimed in claim 1 or 2, wherein the light emitting means are super luminous light emitting diode.
4. An apparatus as claimed in claim 3, wherein the super luminous light emitting diodes are arranged in a cluster on a face of the apparatus.
5. An apparatus as claimed in claim 4, wherein the cluster includes 16 super luminous light emitting diodes emitting light having a wavelength selected from the range 365 to 465 nm, 18 super luminous light emitting diodes emitting light having a wavelength selected from the range of 585 to 645 nm and 18 super luminous light emitting diodes emitting light having a wavelength selected from the range of 646 to 710 nm.

6. An apparatus as claimed in claim 5, wherein the cluster includes 16 super luminous light emitting diodes emitting light having a wavelength of 415 nm, 18 super luminous light emitting diodes emitting light having a wavelength of 635 nm and 18 super luminous light emitting diodes emitting light having a wavelength of 660 nm.
7. An apparatus as claimed in any one of the preceding claims, wherein the light emitting means can irradiate up to 50 cm<sup>2</sup> of skin with light.
8. An apparatus as claimed in claim 7, wherein the light emitting means irradiate 24 cm<sup>2</sup> of skin with light
9. An apparatus as claimed in any one of the preceding claims, wherein the light emitting means has an output of up to 50 mW per cm<sup>2</sup>.
10. An apparatus as claimed in claim 9, wherein the light emitting means has an output of 6 mW per cm<sup>2</sup>.
11. An apparatus as claimed in any one of the preceding claims, wherein the light emitting means emits continuous light and/or pulsed light.
12. An apparatus as claimed in claim 11, wherein the light emitting means emits continuous light and then pulsed light sequentially.
13. An apparatus as claimed in any one of claims 11 or 12, wherein the pulsed light is emitted at a frequency of 18Hz.
14. An apparatus as claimed in any one of claims 11 to 13, further comprising control means for controlling the duration of light being emitted from the light emitting means and/or for switching between the emission of continuous light and pulsed light.



15. An apparatus as claimed in claim 14, wherein the control means causes the light emitting means to emit continuous light for a period of up to 40 minutes and/or pulsed light for a period of up to 40 minutes.

16. An apparatus as claimed in claim 15, wherein the control means causes the light emitting means to emit continuous light for a period of five minutes and then pulsed light for a period of five minutes.

17. A hand-held acne treating apparatus as claimed in any one of the preceding claims.

18. An acne treating apparatus substantially as hereinbefore described with reference to the accompanying drawings.



**Application No:** GB 9923029.4  
**Claims searched:** 1-18

**Examiner:** Anwar Gilani  
**Date of search:** 31 January 2000

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.R): A5R (REHR)

Int CI (Ed.7): A61N 5/06, 5/08

Other: Online: WPI, EPODOC, JAPIO

**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
Y	EP0884066 A2 (SLI LICHTSYSTEME) see WPI abstract	1 at least
A	WO96/14899 A1 (OPTOMED) see WPI abstract and p.12 l.19-25	
Y	US5549660 (MENDES ET AL) col.1 l.47-57, col.3 l.37-45	1 at least
A	DE4440112 A (WILKENS) see WPI abstract	
X	DE4026327 A (GOLF) see WPI abstract	1 at least
X	FR2752739 A (HOME) see WPI abstract	1 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

# (12) UK Patent Application (19) GB (11) 2 360 461 (13) A

(43) Date of A Publication 26.09.2001

(21) Application No 0030974.0

(22) Date of Filing 19.12.2000

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(31) 0009491 (32) 17.04.2000

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United Kingdom

(51) INT CL<sup>7</sup>

**A61N 5/06**

(52) UK CL (Edition S )

**A5R REHR**

(56) Documents Cited

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**WO 01/14012 A WO 00/15296 A US 5616140 A**

(58) Field of Search

**UK CL (Edition S ) A5R REHR**  
**INT CL<sup>7</sup> A61N 5/06**

**ONLINE: EPODOC, WPI, JAPIO**

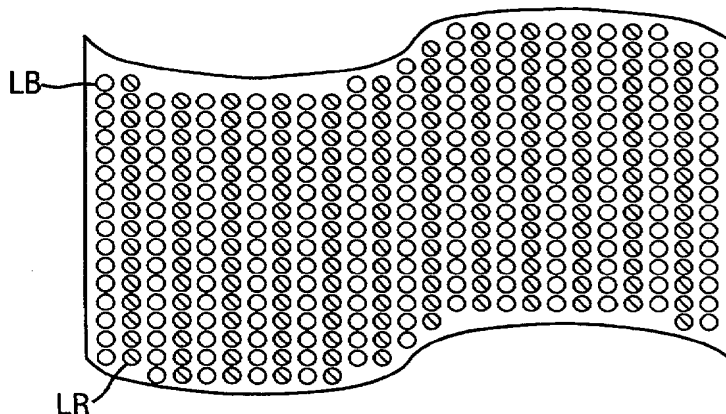
(54) Abstract Title

**Therapeutic light source and method**

(57) A therapeutic light source, for example for photodynamic therapy (PDT), comprises comprising an array of preferably independently switchable red and blue light-emitting diodes L<sub>R</sub>, L<sub>B</sub>, mounted on a flexible backing.

Other arrangements of non-planar arrays of LEDs are also claimed, both for external and internal use as well as light sources comprising LEDs having specific emission wavelengths.

**FIG. 26**



**GB 2 360 461 A**

FIG. 1

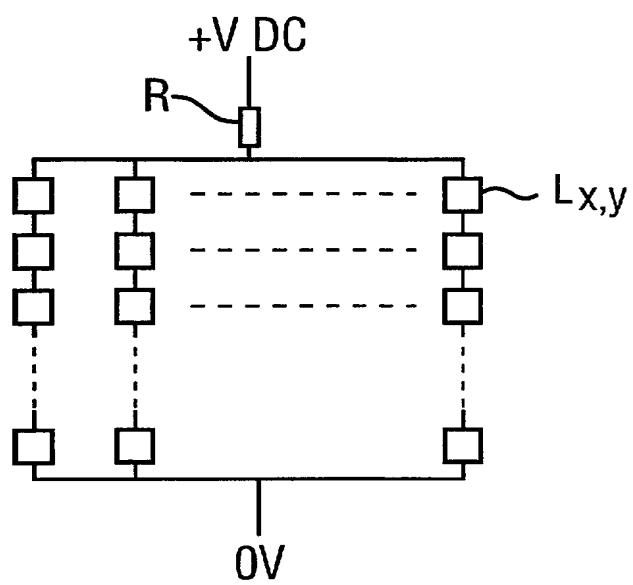


FIG. 5

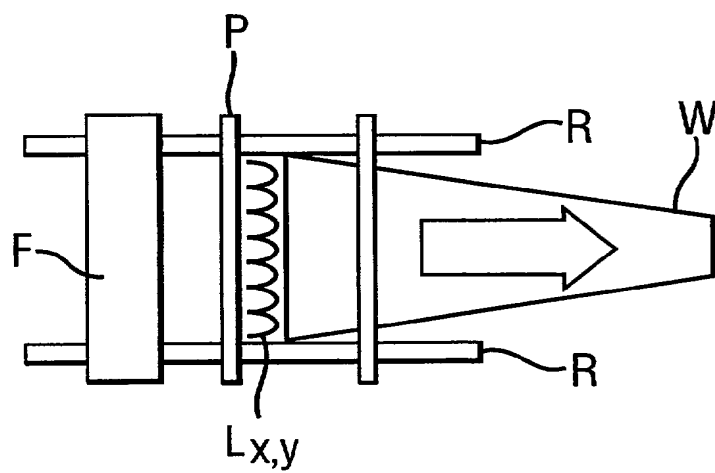


FIG. 2

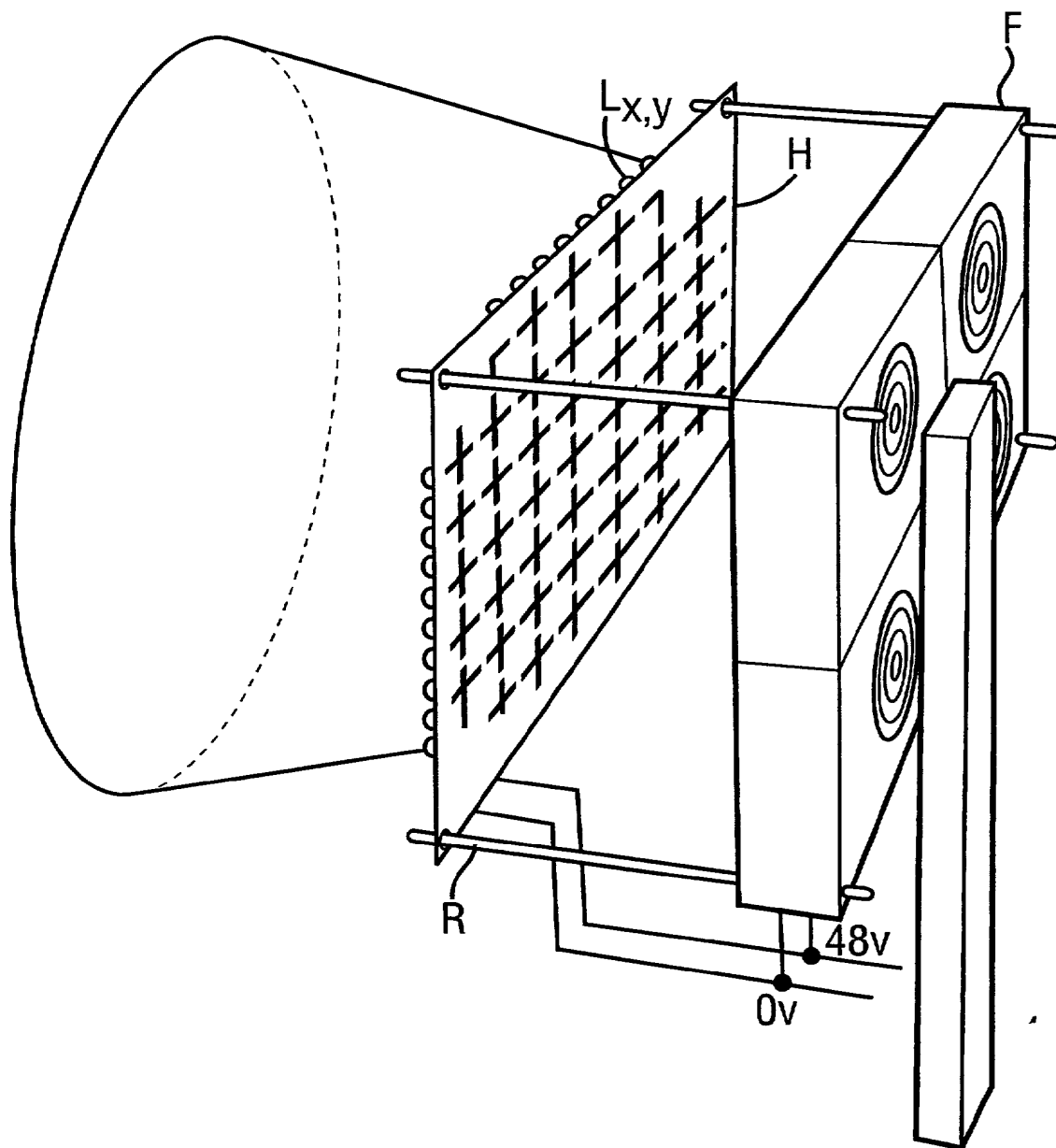


FIG. 3

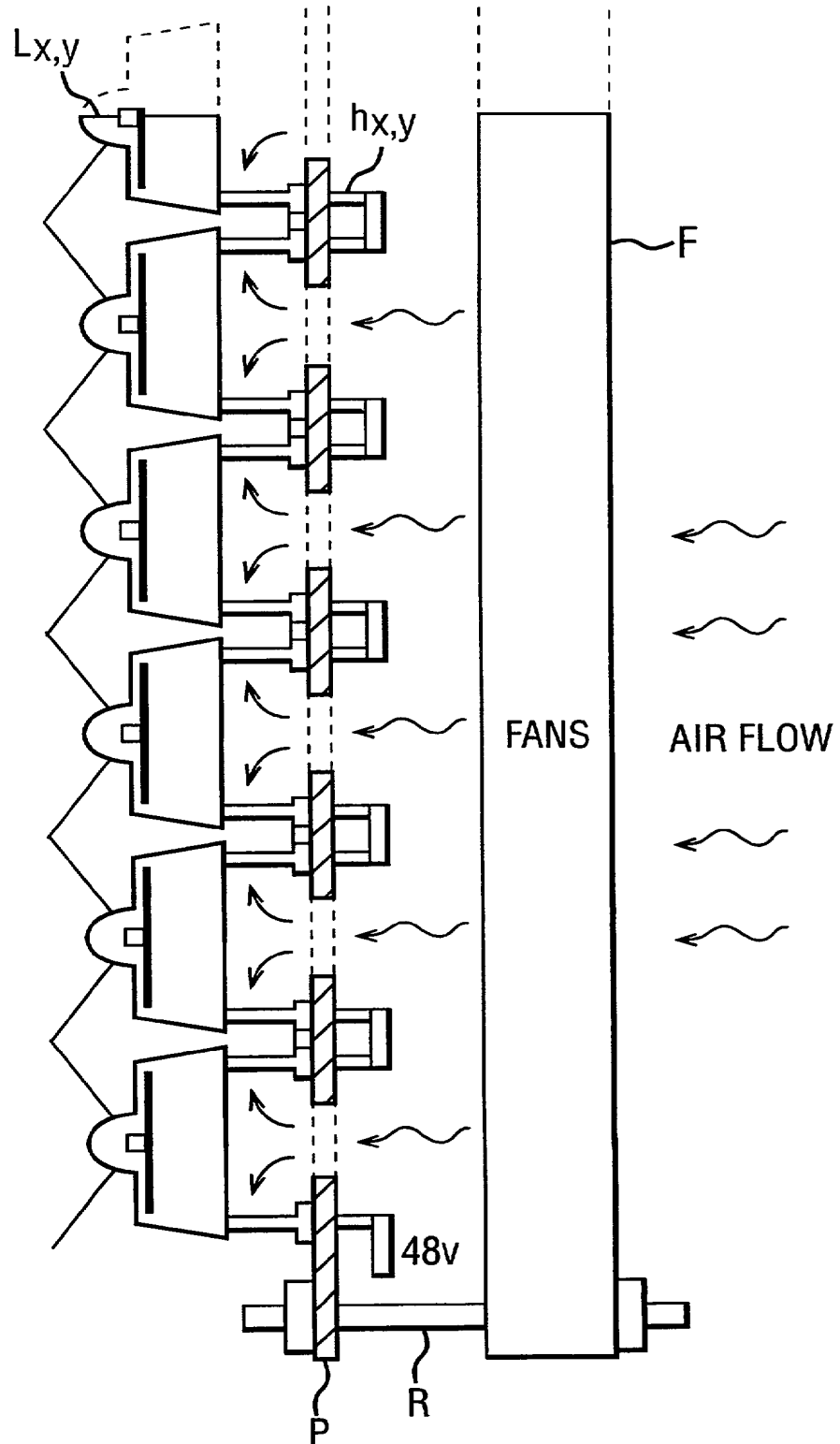


FIG. 4

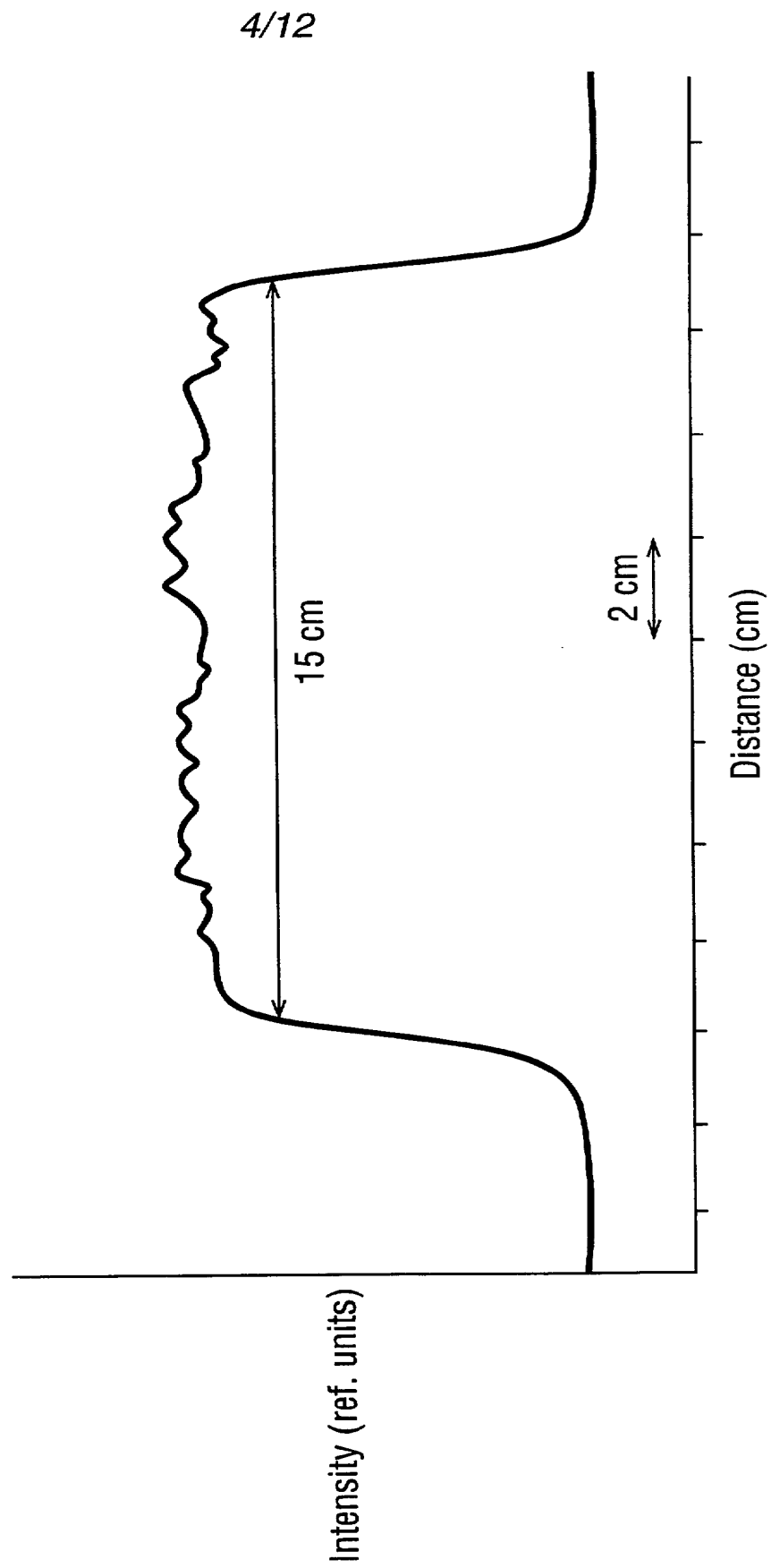


FIG. 6

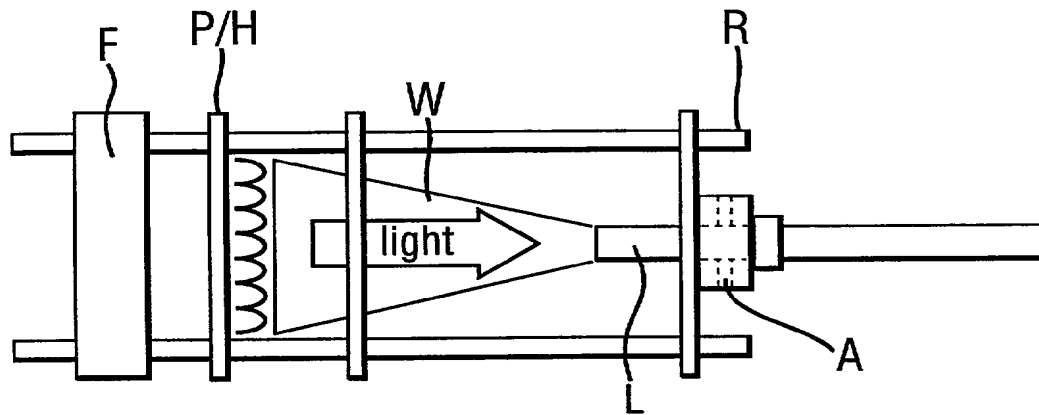


FIG. 7

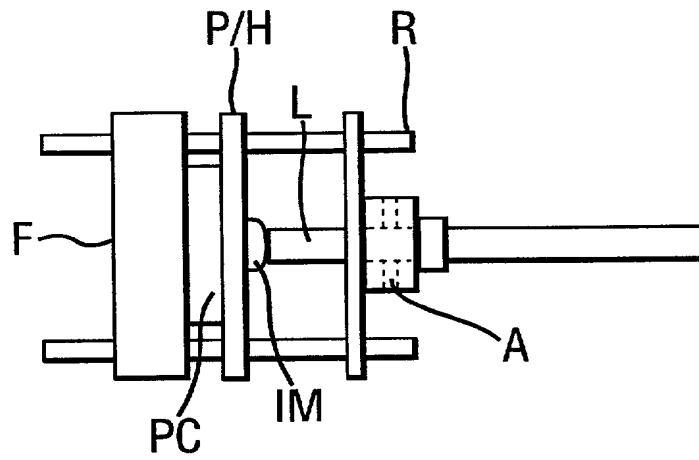


FIG. 8

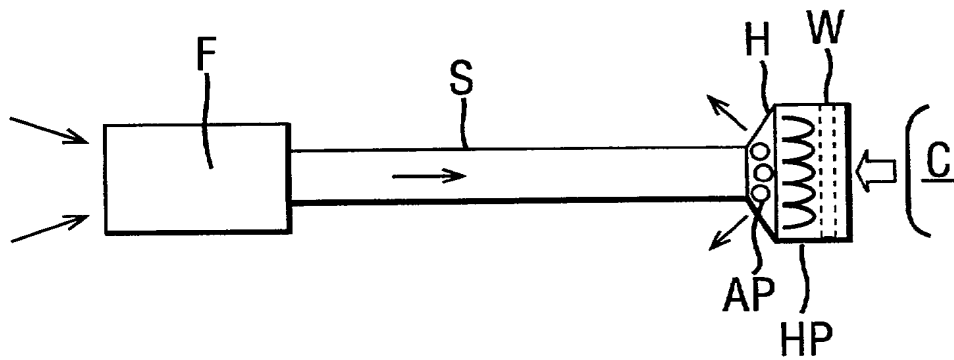




FIG. 9

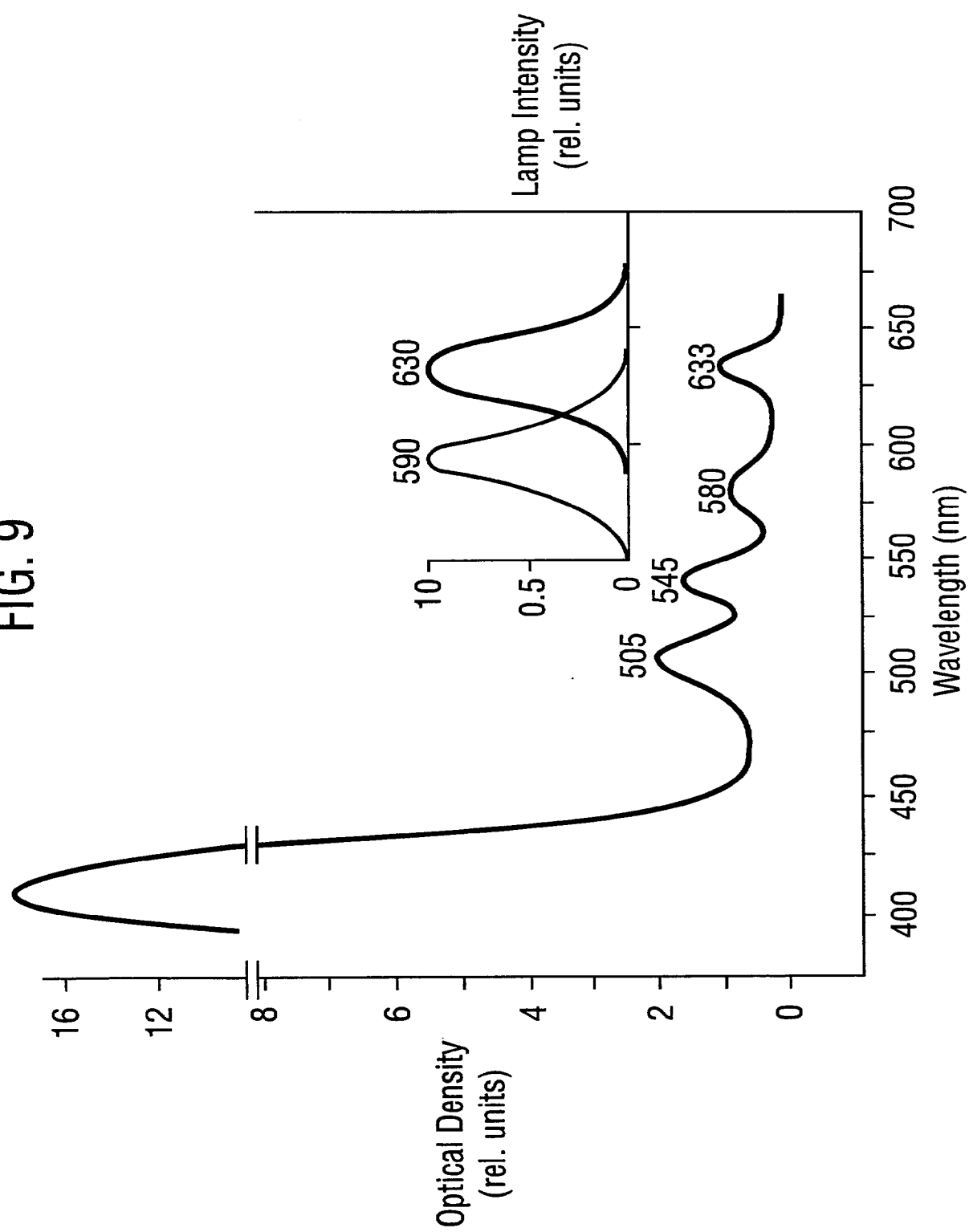


FIG. 10a

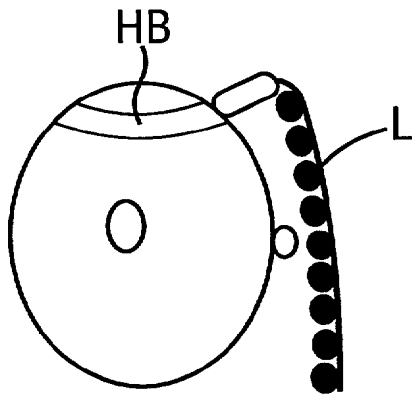


FIG. 10b

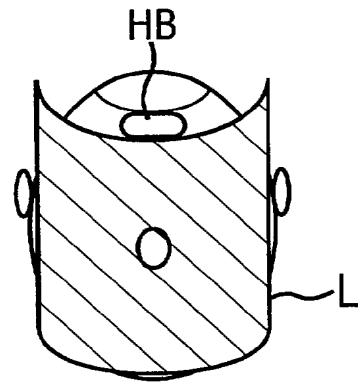


FIG. 11a

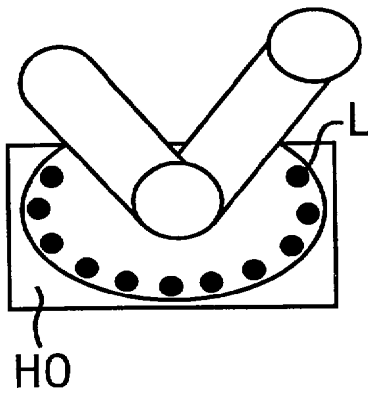


FIG. 11b

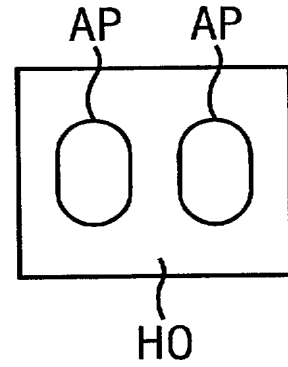


FIG. 11c

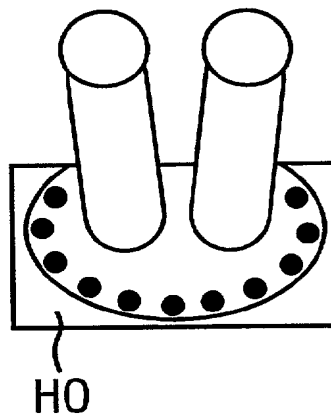


FIG. 12

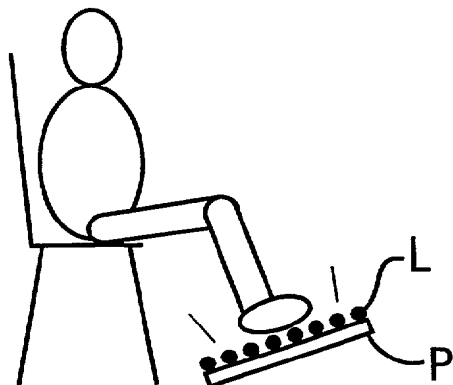


FIG. 13

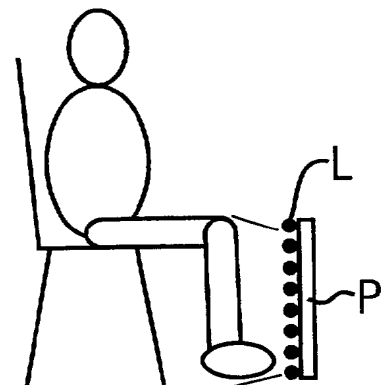


FIG. 14

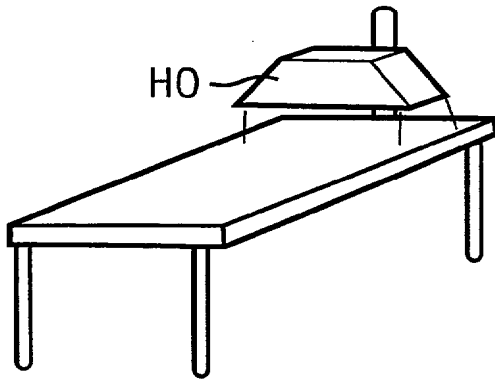


FIG. 15

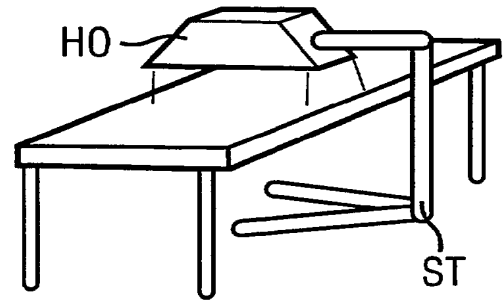


FIG. 16a

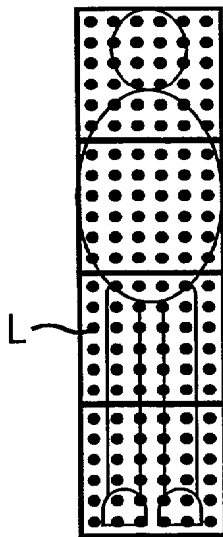


FIG. 16b

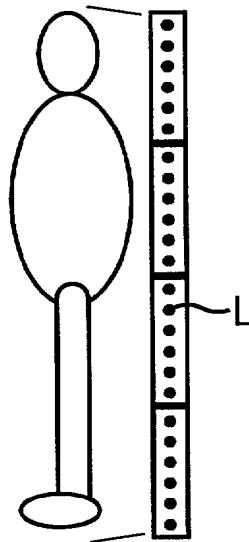


FIG. 17a

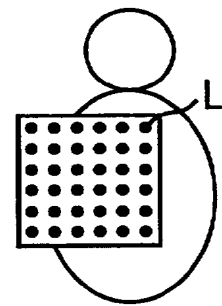


FIG. 17b

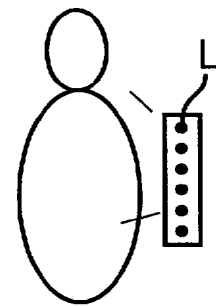


FIG. 18a

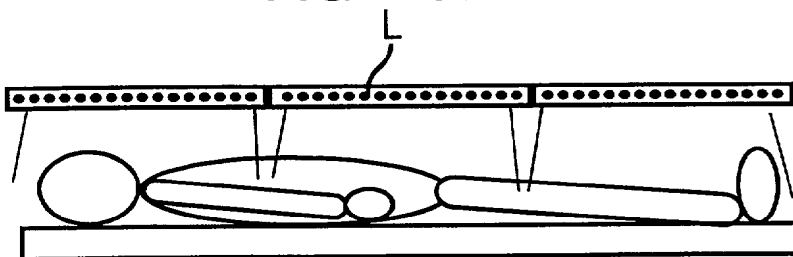


FIG. 18b

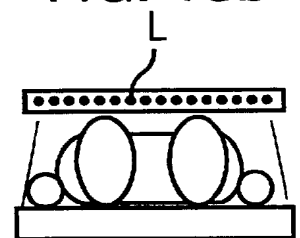


FIG. 19a

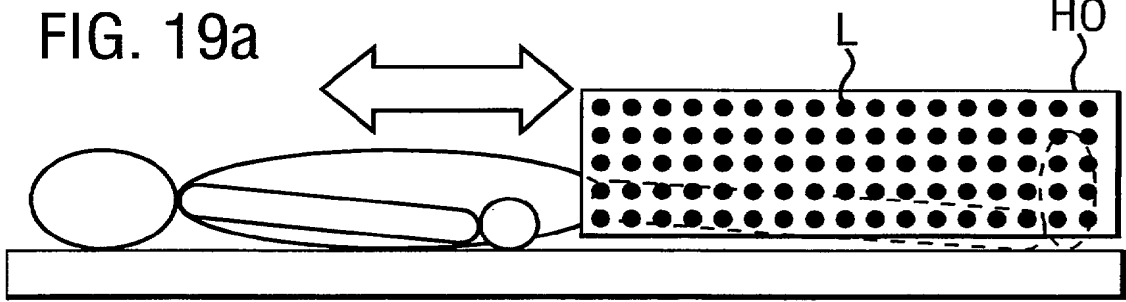


FIG. 19b

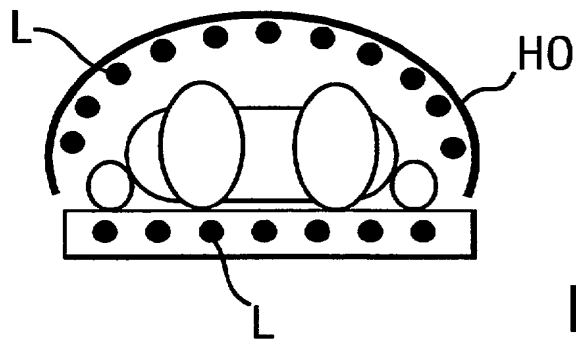


FIG. 20a

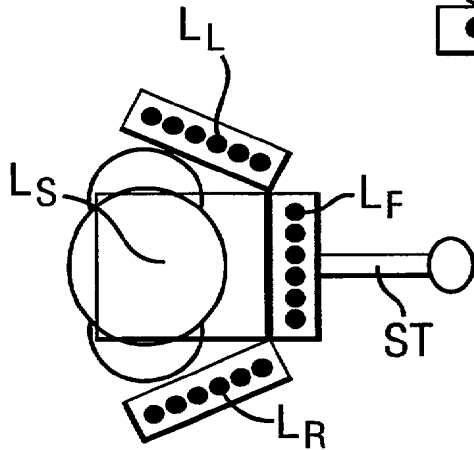


FIG. 20b

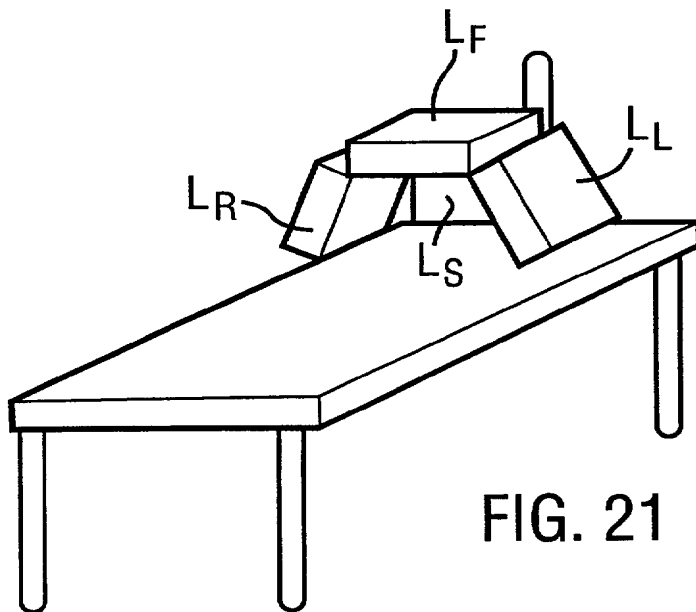
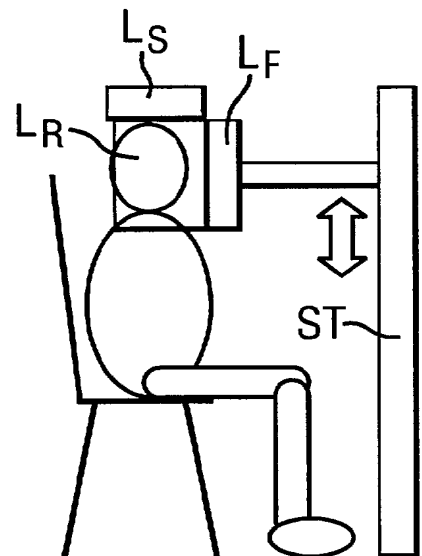


FIG. 21

FIG. 22a

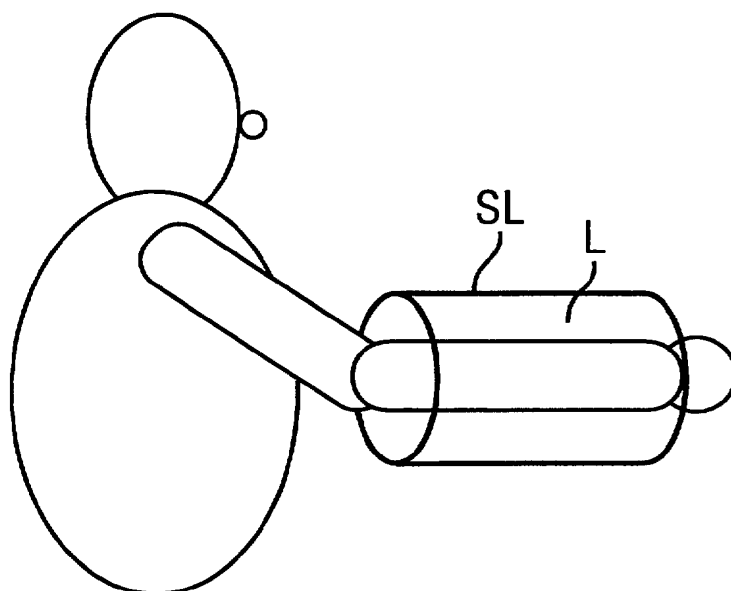


FIG. 22b

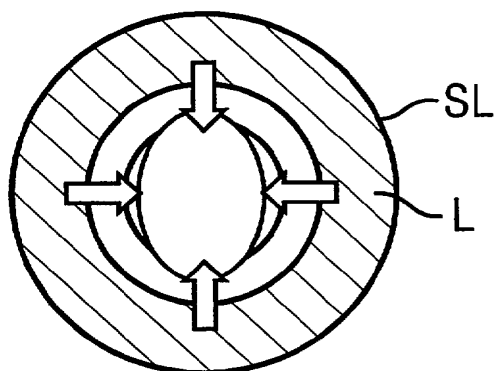


FIG. 22c

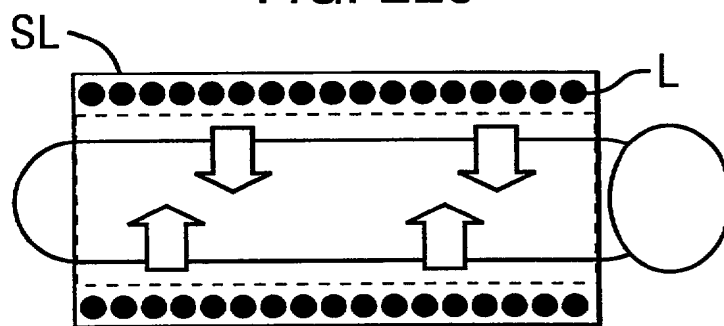


FIG. 23a

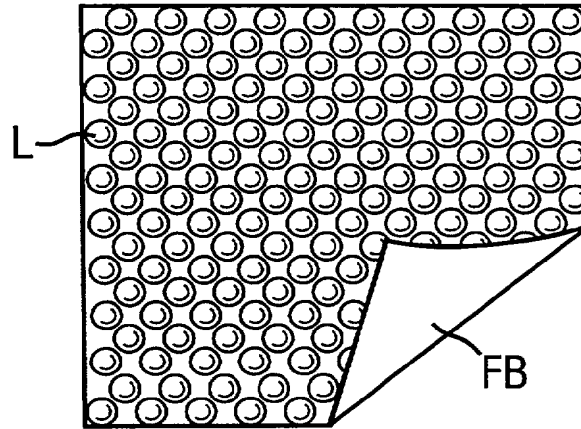


FIG. 23b

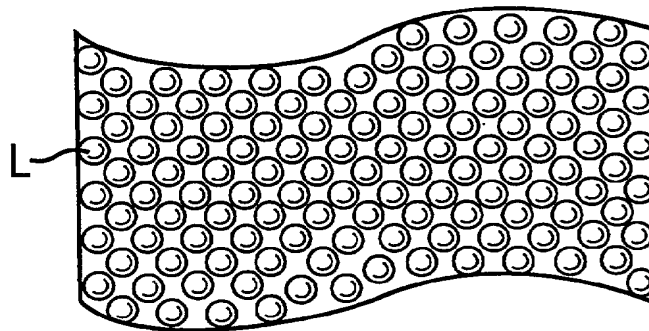


FIG. 23c

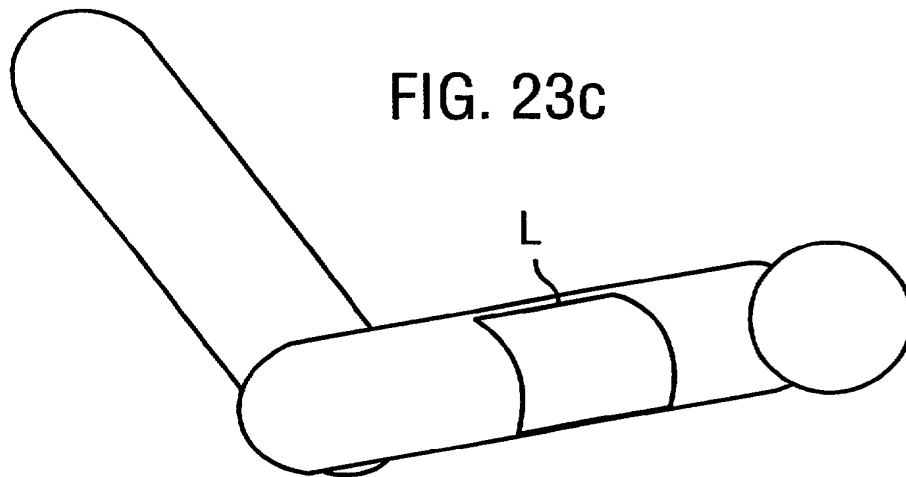


FIG. 24

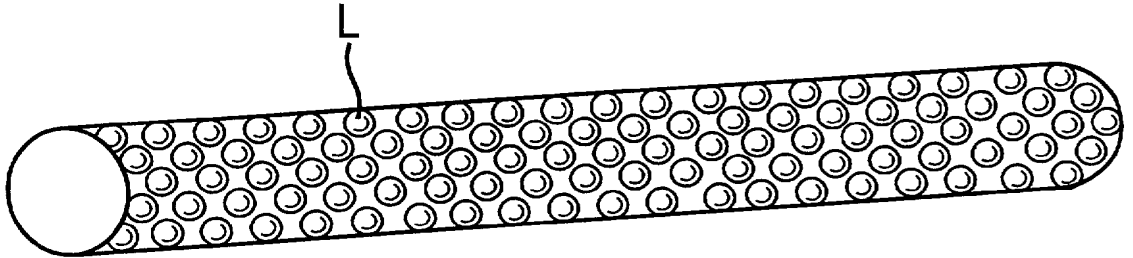


FIG. 25

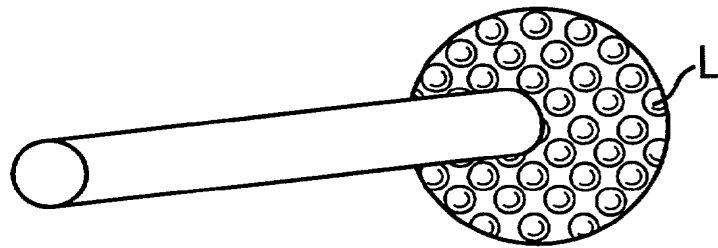
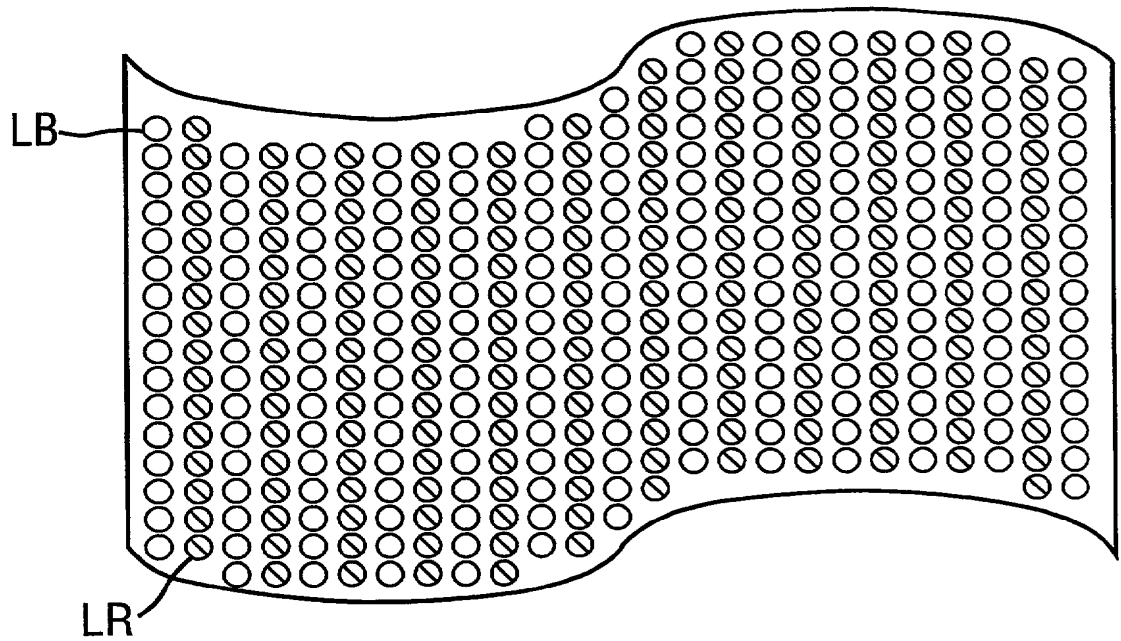


FIG. 26



## THERAPEUTIC LIGHT SOURCE AND METHOD

The present invention relates to a non-coherent light source for use in therapy such as photodynamic therapy (PDT), particularly using light emitting diodes (LED's).

5           Photodynamic therapy involves the administration of a photosensitising drug to an affected area, and its subsequent irradiation with light - see for example 'The Physics of Photodynamic Therapy' by B C Wilson and M S Patterson, Physics in Medicine & Biology 31 (1986) April No. 4, London GB.

10           The document GB 2,212,010 discloses a therapeutic light source which uses an array of discrete LED's as an alternative to lasers or laser diodes. The output of the LED's is focussed so as to provide the necessary intensity.

15           The document WO 94/15666 discloses a therapeutic light source specifically for PDT, with an integrated array of LED's mounted on the distal end of a hand piece. The LED's are overdriven to give the necessary intensity, and cooled by the flow of water around a closed loop passing along the hand piece. The document US 5728090 discloses a somewhat similar device with various different types of head containing integrated LED matrices. These  
20           devices require complicated liquid cooling circuits which would add to the cost of the device and add to the bulk of the hand piece, which is disadvantageous for invasive use.

25           The document US 5728090 mentions that the wavelength of the LED's is between 300 nm and 1300 nm and is selected based upon the particular photosensitive dye used during PDT. However, the wavelengths of LED's capable of providing the necessary intensity for PDT cannot freely be chosen within that range.

          According to one aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a non-planar array of



light-emitting diodes conforming with the shape of an external area to be treated or diagnosed.

According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably  
5 connected thereto.

According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to  
10 cover at least part of the length of a patient.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being  
15 arranged to direct light onto the part of the patient's body when inserted into the housing.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of  
20 an arm and/or hand of a patient when inserted into the sleeve.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on the surface thereof an array of discrete light-emitting diodes.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an air-cooled array of LED's, the air being vented in the vicinity of the array. In one embodiment, the array is mounted at the distal end of a hand piece suitable for invasive therapy.

According to another aspect of the present invention, there is provided  
30 a therapeutic light source comprising an array of LED's coupled to a light

guide for delivering the light to the area to be treated. Preferably, the LED's are directly coupled without intervening optical devices.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with emission spectra  
5 substantially limited to the range 550 to 660 nm, and preferably to one of the ranges 590 to 640 nm, 560 to 644 nm, 650 to 660 nm, and 550 to 570 nm.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm, 470 nm, 505 nm or 525 nm.

10 Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a diagram of a parallel-series matrix of discrete LED's used in first and second embodiments of the present invention;

Figure 2 is perspective diagram of the first embodiment;

15 Figure 3 is a cross section of part of the first embodiment;

Figure 4 is a graph showing the variation of intensity in a cross-section of the output of the first embodiment;

Figure 5 is a cross-sectional diagram of a second embodiment;

Figure 6 is a cross-sectional diagram of a third embodiment;

20 Figure 7 is a cross-sectional diagram of a fourth embodiment;

Figure 8 is a cross-sectional diagram of a fifth embodiment;

Figure 9 is a graph showing the absorption spectrum of PpIX and the emission spectra of two examples of LED's suitable for use with the embodiments;

25 Figures 10a and 10b are side and front views respectively of an LED array in a sixth embodiment for treatment of the face;

Figures 11a, 11b and 11c are a cross-section in the plane of the patient's arm, a top view and a vertical cross-section transverse to the patient's arm of an LED array in a seventh embodiment for treatment of the  
30 elbows of a patient;

Figure 12 is a side view of an LED array in an eighth embodiment used for treatment of the foot or feet;

Figure 13 is a side view of an LED array in a ninth embodiment used for treatment of the lower leg;

5        Figures 14 and 15 show arrangements of an LED array in tenth and eleventh embodiments for treatment of respectively the face and a section of a patient lying on a bed;

      Figures 16a and 16b show respectively front and side views of a set of similar LED arrays in an twelfth embodiment for treatment of one side of a  
10       patient;

      Figures 17a and 17b show respectively front and side views of an LED array in a thirteenth embodiment for treatment of a section of one side of a patient;

      Figures 18a and 18b are respectively side and end views of a set of  
15       similar LED arrays in a fourteenth embodiment, for treatment of one side of a patient lying down;

      Figures 19a and 19b are respectively side and end views of an LED array in a fifteenth embodiment for treatment of a section of a patient lying down;

20       Figures 20a and 20b are top and side views respectively of an arrangement of LED arrays in a sixteenth embodiment for treatment of the face and/or scalp;

      Figure 21 shows a similar arrangement to that of Figures 20a and 20b, in a seventeenth embodiment for treatment of the face and/or scalp of a patient  
25       lying down;

      Figures 22a, 22b and 22c show respectively a side view, a transverse cross-section and a longitudinal cross-section of an LED array arranged within a sleeve in a eighteenth embodiment, for treatment of the hand, forearm and/or elbow;

Figures 23a, 23b and 23c show respectively two different shapes of flexible LED array, and a flexible array applied as a patch onto the skin of a patient, in an nineteenth embodiment;

5 Figure 24 shows an LED array arranged on the side of a cylindrical intraluminal probe in a twentieth embodiment;

Figure 25 shows an LED array arranged on the surface of a spherical intraluminal probe in a twenty-first embodiment; and

Figure 26 shows a more specific example of the flexible LED array in the nineteenth embodiment.

10 In a therapeutic light source in the first embodiment, as illustrated in Figures 1 to 5, light is emitted from a parallel-series matrix of LED's L connected through a current-limiting resistor R to a source of a voltage +V. The LED matrix is mounted on a heatsink array H parallel to and spaced apart from a fan array F by support rods R. Air is blown by the fan array F onto the  
15 back of the heatsink array H.

As shown in more detail in Figure 3, the heatsink array H comprises a plurality of individual heatsinks h mounted on the ends of the legs of the LED's, which pass through a support plate P. Each leg is soldered to an adjacent leg of another of the LED's in the same column. The support plate P  
20 is perforated to allow air to flow more freely around the heatsinks h and the LED's L.

The LED's L are arranged so as to produce a substantially uniform illumination of  $\pm 10\%$  or less across a treatment field by selecting the beam divergence and spacing of the LED's L so that their individual beams overlap  
25 without causing substantial peaks or troughs in intensity. In the example shown in Figure 4, uniformity of  $\pm 6\%$  is achieved. In this embodiment, no optical system is needed between the LED's and the patient; instead, the light is emitted directly from the LED's onto the patient. As the light is not concentrated by any optical system, the LED's have individual power outputs  
30 of at least 5 mW and preferably at least 10 mW, to give the necessary fluence

rates in the treatment field of at least  $30 \text{ mW/cm}^2$  in the red region of the spectrum and at least  $10 \text{ mW/cm}^2$  in the blue region.

In one specific example, a 15 cm diameter array of 288 'Super flux' LED's was used to produce a total light output of 8 W at  $45 \text{ mW/cm}^2$  in the treatment field. The LED's were driven at a higher current load than their specification while being cooled by forced air convection from the fans F. In the specific example, the current was limited to 90 mA per column of diodes, but may be increased to 120 mA or more if increased light output is needed. The number of diodes in series, in each column, is selected so that the total forward operating voltage is as close as possible to, but less than, the power supply output voltage, in this case 48 V. This arrangement avoids wasteful in-circuit heating and maximizes the operating efficiency of the electrical system.

A method of treatment for oncological and non-oncological skin diseases such as cases of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism, using the first embodiment, will now be described. A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected area of the skin of the patient, or administered intravenously or orally. In another method of application for large areas, the patient may be immersed in a bath of solution. The affected area may then be covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is then uncovered and exposed to light from the lamp according to the first

embodiment for a period of 15 to 30 minutes. The treatment may then be repeated as necessary, for a total of 1 to 3 treatments. This method is particularly suitable for the treatment of patients with very large lesions or multiple lesions extending over a large area.

5           In a method of treatment using the device of the first embodiment, the LED array is positioned approximately parallel to an external affected area of a patient to be treated, with a separation sufficient to achieve the uniform illumination as shown in Figure 4, for example 2 to 5 cm. The device may also be used for cosmetic or partially cosmetic treatment with a  
10       photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

          The lamp may also be used for fluorescence detection (photodiagnosis).

15           The first embodiment may be modified in a second embodiment, as shown in Figure 5, by the addition of a frusto-conical waveguide W, for example of acrylic (e.g. Perspex™) or glass, supported by the support rods R, which are extended in this embodiment. The waveguide W is arranged to concentrate light emitted by the LED's onto a smaller area with higher  
20       intensity. This arrangement is suitable for treating smaller external surfaces.

          The second embodiment may be modified in a third embodiment, as shown in Figure 6, to deliver the light from the waveguide W into a lightguide L for internal treatment. The lightguide L, such as an optical fibre or fibre bundle, or liquid light guide, is held in a lightguide receptacle or adapter A,  
25       that is compatible for example with Olympus, Storz, ACMI or Wolf light cable fittings, in abutment or immediately adjacent relation with the narrow end of the waveguide W. The lightguide L may be of 3, 5 or 8 mm diameter. The support rods R align the optical axes of the waveguide W and lightguide L, so that the light emitted by the waveguide W is launched into the lightguide  
30       L. In the third embodiment, the light is concentrated by the waveguide and

emitted over a small area at the distal end of the lightguide L which may be inserted into body cavities for oral, gynaecological, gastrointestinal or intraluminal treatment.

The third embodiment may be modified in a fourth embodiment, as shown in Figure 7, in which the discrete LED array is replaced by an integrated multi-die LED matrix IM (for example part no. OD 6380, OD 6624 or OD 6680 available from AMS Optotech, Bristol, UK) mounted on the support plate/heatsink P, H. A Peltier effect thermoelectric cooler PC is mounted in thermal contact with the opposite side of the support plate P, the heated side of which is cooled by the fan F. The proximal end of the lightguide L is directly adjacent or abutting the integrated LED matrix IM, which are of similar cross-section so that the waveguide is not needed to launch the emitted light into the lightguide L.

A fifth embodiment, as shown in Figure 8, is designed specifically for treatment of the cervix, such as PDT treatment. The fifth embodiment has the form of a hand piece having a hollow stem S, for example of acrylic or polycarbonate, through which air is blown at low pressure by a fan F mounted at the proximal end. The distal end has a head portion HP comprising a housing within which is mounted a discrete LED array mounted on a support plate/heatsink P/H. Air passes through the hollow stem S onto the heatsink H so as to extract heat therefrom and is then vented through apertures AP on the proximal side of the housing. The distal end of the housing is concave and dimensioned so as to fit closely over the end of the cervix C. A transparent end window W, for example of acrylic or glass, prevents infiltration of the LED's. Power is carried to the LED's through wires (not shown) mounted on the wall of the acrylic stem S. In use, the hand piece is positioned so that the distal end fits over the cervix of the patient and is clamped in position for the duration of the treatment.

The selection of appropriate discrete LED's for PDT using any of the first to fourth embodiments will now be described, grouped according to die material.

A first suitable type of LED is based on aluminium indium gallium phosphide/gallium phosphide (AlInGaP/GaP) of transparent substrate (TS) or absorbing substrate (AS) type. The output wavelengths are in the range 590 to 640 nm with peak emission wavelengths of 590, 596, 605, 615, 626, 630 and 640 nm. Commercially available examples are the 'SunPower'<sup>TM</sup> or 'Precision Optical Power'<sup>TM</sup> series from Hewlett Packard Company, designed for use in the automotive industry, for commercial outdoor advertising and traffic management. Suitable LED's are those packaged as: SMT (surface mount technology) e.g. HSMA, HSMB, HSMC, HSML series and preferably HSMB HR00 R1T20 or HSMB HA00R1T2H; Axial e.g. HLMA or HLMT series; T1 e.g. HLMP series, preferably HLMP NG05, HLMP NG07, HLMP J105; T13/4 e.g. HLMP series, preferably HLMP DG08, HLMP DG15, HLMP GG08, HLMP DD16; Superflux<sup>TM</sup> e.g. HPWA or HPWT series, preferably HPWA (MH/DH/ML/DL) 00 00000, HPWT (RD/MD/DD/BD/RH/MH/DH/BH/RL/ML/DL/BL) 00 00000, most preferably HPWT (DD/DH/DL/MH/ML/MD) 00 00000; SnapLED<sup>TM</sup> e.g. HPWT, HPWS, HPWL series, preferably HPWT (SH/PH/SL/PL) 00, HPWT (TH/FH/TL/FL) 00 or HPWS (TH/FH/TL/FL) 00. Suitable products from other manufacturers include: of SMT type, Advanced Products Inc. (API) part no. HCL4205AO; of T1 type, American Bright Optoelectronics (ABO) part no. BL BJ3331E or BL BJ2331E; of Superflux type, ABO part no.'s BL F2J23, BL F2J33 and BL F1F33.

A second suitable type of LED is the aluminium indium gallium phosphide/gallium arsenic (AlInGaP/GaAs) type, with emission wavelengths in the range 560 to 644 nm and peak emission wavelengths of 562 nm, 574 nm, 590 nm, 612 nm, 620 nm, 623 nm and 644 nm. Examples commercially available from Toshiba in T1 package are the TLRH, TLRE, TLSH, TLOH or



TLYH series, preferably TLRH 262, TLRH 160, TLRE 160, TLSH 1100, TLOH 1100, TLYH 1100 or S4F4 2Q1; or in T13/4 package are the TLRH or TLSH series, preferably TLRH 180P or TLSH 180P. Another example is Kingbright L934SURC-E.

5           A third suitable type of LED is aluminium gallium arsenic type (AlGaAs), with emission wavelengths in the range 650 to 660 nm. Examples in T1 package include the Toshiba TLRA series, preferably TLRA 290P or TLRA 293P, and Kingbright L934 SRCG, L934 SRCH, and L934 SRCJ and in T13/4 package include Kingbright L53 SRCE.

10           A fourth suitable type of LED is gallium phosphide (GaP) type, with emission wavelengths in the range 550 to 570 nm.

          A fifth suitable type of LED is indium gallium nitride (InGaN). In the type with an emission wavelength of 525 nm, commercially available examples include: in SMT package, API's HCL 1513AG; and in T1 package, 15 Farnell's #942 467, Radio Spare's #228 1879 and #249 8752, API's HB3h 443AG and Plus Opto's NSPG500S. In the type with emission wavelengths of 470 and 505 nm and T1 package type, examples are Farnell's #142 773, Radio Spare's #235 9900 and American Bright Optoelectronics Inc.'s BL BH3PW1.

          A sixth suitable type of LED is gallium nitride/silicon (GaN/Si), with 20 an emission wavelength of 430 nm. One commercial example is Siemens LB3336 (also known as RS #284 1386).

          Each of the above LED types is selected to have an emission spectrum substantially coincident with the absorption spectrum of one or more of the following common photosensitizers given below in Table 1, and therefore 25 embodiments having such LED's are suitable for PDT. For example, Figure 9 shows the absorption spectrum of PpIX, including peaks at 505nm, 545 nm, 580 nm and 633 nm. Inset are the emission spectra, in units of peak intensity and on the same wavelength axis, of LED part no. HPWA DL00 with a peak at 590 nm and LED part no. HPWT DH00 with a peak at 630 nm, the peaks

having sufficient breadth to give a substantial overlap with the 580 nm and 633 nm peaks respectively in the absorption spectrum of PpIX.

Table 1

Photosensitizer	Red absorption Band (nm)	Red Peak (nm)	Blue/Green Peak (nm)
Naphthalocyanines	780-810		
Chalcogenopyriliun dyes	780-820		
Phthalocyanines (e.g. ZnII Pc)	670-720	690	
Tin etiopurpurin (SnET <sub>2</sub> )	660-710	660-665	447
Chlorins (e.g. N-Aspartyl chlorin e6 or NPe6)	660-700	664	
Benzoporphyrin derivative (BPD)		685/690	456
Lutetium texaphrin (Lu-Tex)		735	
Al(S <sub>1</sub> /S <sub>2</sub> /S <sub>3</sub> /S <sub>4</sub> ) Pc	660-710	670/685	410, 480
Photofrin		625/630	405
Protoporphyrin IX (PpIX) - from 5/δAminolaevulinic Acid (5ALA)		635	410, 505, 540, 580
Tetra m-hydroxyphenyl Chlorin (mTHPC)		650	440, 525

5

The discrete LED array may comprise more than one different type of LED, each with different emission spectra, selected to match different absorption bands of the selected photosensitizer. Each type of LED may be switched independently. The penetration depth (i.e. the depth at which the intensity has been attenuated to  $e^{-1}$ ) may also be varied by switching on only one type of LED in the array so as to select a suitable emission band, since the penetration depth is a function of the wavelength.

10

The LED array may be composed of individually switchable spatially distinct segments of LED's. Selected segments may be switched on so as to treat a selected area of the patient within the overall area of the matrix array.

5 The lamp may include an electro-optical detector arranged to monitor the light dose delivered and to switch off the light emission when a target dose is reached. Alternatively, or additionally, the detector is arranged to monitor the instantaneous light intensity and to vary the electrical power supplied to the tubes so as to maintain the intensity within predetermined limits, and/or to switch off the light emission if a maximum limit is exceeded.

10 Various different arrangements of LED array suitable for treatment of different areas of a patient will now be described. The LED's are discrete LED's as described above. Except where stated otherwise, the LED's may be fan-cooled using integrated fans.

15 Figures 10a and 10b show an array of LED's L in a sixth embodiment, arranged on a support P shaped as a curved visor for treatment of the face of a patient. The array is supported in front of the patient's face by a head band HB or other head wear worn by the patient.

20 Figures 11a to 11c show an array of LED's L in a seventh embodiment arranged within a cuboid housing HO which has two similar apertures AP on one face, to allow the elbows to be inserted into the housing HO. The edges of the apertures AP are cushioned to allow the arms to be rested comfortably. Within the housing HO is arranged a surface SU which is curved both in the plane of the arms and perpendicular to that plane, as shown in Figure 11c. The LED's L are mounted on this surface SU so that light emitted therefrom is  
25 concentrated onto the elbows of the patient.

Figure 12 shows an LED array L in an eighth embodiment mounted on a support plate P, and covered by a transparent or translucent cover on which the foot or feet of the patient rest during treatment.

30 Figure 13 shows an LED array L in a ninth embodiment mounted on a support plate P and arranged for treatment of the lower leg of a patient.

Figures 14 and 15 show an LED array L, mounted in a housing HO in the form of a trapezoid prism, the upper inner surface carrying the LED array and the lower surface being open to allow light to fall onto the patient. The side faces may be reflective, or carry additional LED arrays. In the tenth embodiment shown in Figure 14, the housing HO is mounted at one end of a bed so that its height above the bed is adjustable, for facial treatment of a patient lying on the bed. In the eleventh embodiment shown in Figure 15, the housing HO is mounted on a stand ST and is adjustable in height, for treatment of a selected part of a patient lying on the bed.

Figures 16a and 16b show a series of four coplanar LED arrays L in a twelfth embodiment arranged to treat one side of a patient. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

Figures 17a and 17b show a single LED array L in a thirteenth embodiment positioned to treat a section of the patient.

Figures 18a and 18b show a series of three coplanar LED arrays L in a fourteenth embodiment arranged to treat one side of a patient lying down. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

Figures 19a and 19b show an array of LED's L in a fifteenth embodiment mounted on the inner surface of a curved housing HO for treatment of a patient lying on a further, planar array of LED's, for treatment of a section of the patient from all sides. The housing HO is slidable along the length of the patient so as to treat a selected area of the patient. Sections of the planar array of LED's are switchable so as to illuminate only the selected section.

Figures 20a and 20b show a sixteenth embodiment comprising a front-facial LED array  $L_F$  for directing light onto the face of the patient from the front, a scalp LED array  $L_S$  and left and right side-facial LED arrays  $L_L$ ,  $L_R$  moveably connected, for example by hinges, to the front-facial array  $L_F$ , for

directing light onto the scalp, left side of the face and right side of the face respectively. The front-facial array  $L_F$  is slideably attached to a stand ST for vertical adjustment to the head height of the patient, preferably when sitting.

Figure 21 shows a seventeenth embodiment, similar to that of Figures 20a and 20b, except that it is arranged for facial and/or scalp treatment of a patient when lying down. The stand ST is mounted on a bed, instead of being free-standing, and the arrays are rotated by  $90^\circ$  so as to correspond to the position of the patient's head when lying down.

Figures 22a, 22b and 22c show an eighteenth embodiment in which an LED array L is mounted on the inner surface of a sleeve SL so as to direct light onto the hand, forearm and/or elbow within the sleeve.

Figures 23a and 23b show respectively a square and a rectangular LED array L in a nineteenth embodiment mounted on a flexible backing member FB which can be applied to an area of the patient to be treated, such as part of the forearm as shown in Figure 23c, with the LED's facing inwardly. The LED array thereby follows the contours of the area to be treated. The flexible backing member FB may be cooled by a fan which is either discrete or connected thereto by a flexible membrane which is fixed around the flexible backing member FB and directs air from a fan onto the backing member, through which the air is vented.

Figure 24 shows an LED array in a twentieth embodiment arranged on the surface of a cylindrical intraluminal probe, while Figure 25 shows an LED array in a twenty-first embodiment arranged on the surface of a spherical head of an intraluminal probes. The probes are dimensioned for vulval, cervical, endometrial, bladder, gastrointestinal, oral, nasal, aural and/or bronchial treatment.

In tests performed by the inventor, the efficacy of PDT using red (approximately 630 nm) emission from LED's was established in *in-vivo* comparative studies using a sub-cutaneous mammary tumour regrowth delay assay. Using radiobiological end-points, it was shown that the solid-state

prototype efficacies were comparable to that of expensive conventional lasers for PDT (i.e. no significant difference,  $p=0.21$ ). These results were confirmed in further clinical studies in the treatment of Bowen's disease and basal cell carcinomas where comparative complete response rates were achieved as compared to laser PDT.

Figure 26 shows a more specific example of the nineteenth embodiment, consisting of rows of blue LED's  $L_B$  interspersed with rows of red LED's  $L_R$  so as to form a discrete LED array composed of different types of LED as described above. The blue LED's  $L_B$  are switchable on and off together, independently of the red LED's  $L_R$  which are also switchable on and off together. In this way, red or blue illumination may be chosen according to the type of treatment and penetration depth required.

The blue LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 370 to 450 nm, and preferably 400 to 430 nm. This range is particularly suitable for the treatment of pre-cancerous conditions, in particular actinic keratoses.

The red LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 620 to 700 nm. This range is particularly suitable for the treatment of non-melanoma, such as basal cell or squamous cell carcinoma, or mycosis fungoides.

## CLAIMS

1. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on a flexible backing, the array including light-emitting diodes of a first type having a first emission spectrum and light-emitting diodes of a second type having a second emission spectrum different from the first emission spectrum.
2. A light source according to claim 1, wherein said light-emitting diodes of the first type are independently switchable from said light-emitting diodes of the first type.
3. A light source according to claim 1 or 2, wherein said first emission spectrum is substantially in the range 370 to 450 nm.
4. A light source according to claim 3, wherein said first emission spectrum is substantially in the range 400 to 430 nm.
5. A light source according to any preceding claim, wherein said second emission spectrum is substantially in the range 620 to 700 nm.
6. Use of a light source according to any preceding claim, in the treatment of a pre-cancerous condition.
7. Use according to claim 6, wherein said pre-cancerous condition is an actinic keratosis.

8. Use of a light source according to any one of claims 1 to 5, for the treatment of a non-melanoma.
- 5 9. Use according to claim 8, wherein said non-melanoma is a basal cell or squamous cell carcinoma.
- 10 10. A light source for therapy and/or diagnosis, comprising a non-planar array of light-emitting diodes conforming with the shape of an external area of a patient to be treated or diagnosed.
11. A light source as claimed in claim 10, wherein said array is mounted on a head portion for attachment to the head of a patient.
- 15 12. A light source as claimed in claim 10, wherein said array is mounted on a flexible support for attachment to the external area.
- 20 13. A light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.
- 25 14. A light source as claimed in claim 13, further including a third array of light-emitting diodes movably connected to the first array.
15. A light source as claimed in claim 14, further including a fourth array of light-emitting diodes movably connected to the first array.
16. A light source as claimed in any one of claims 13 to 15, arranged for treatment of the face and/or scalp.



17. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.
- 5 18. A light source as claimed in claim 17, further comprising an array of light-emitting diodes arranged for positioning beneath the patient.
- 10 19. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.
- 15 20. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.
- 20 21. A light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on a surface thereof an array of discrete light-emitting diodes.
- 25 22. A light source as claimed in claim 21, wherein said surface is substantially cylindrical.
23. A light source as claimed in claim 21, wherein said surface is substantially spherical.

24. A light source for therapy or diagnosis, comprising an array of light-emitting diodes arranged to give an output intensity of at least approximately  $10 \text{ mW/cm}^2$  in a treatment field, and means for cooling the diodes by forced air convection.
- 5
25. A light source as claimed in claim 24, arranged so that light from the light-emitting diodes is incident directly on the treatment field with a spatial intensity fluctuation of approximately 10% or less.
- 10
26. A light source as claimed in claim 24 or 25, wherein the diodes are thermally coupled to one or more heatsinks.
27. A light source as claimed in claim 24, wherein the diodes are mounted at the distal end of a passage for carrying the air from the proximal to the distal end.
- 15
28. A light source as claimed in claim 27, including a fan mounted at the proximal end of the passage.
- 20
29. A light source as claimed in claim 27 or claim 28, wherein the distal end is dimensioned so as to be locatable proximate the cervix of a patient such that light from the diode array is incident on the cervix.
- 25
30. A light source as claimed in claim 29, wherein the distal end is concave so as to fit over the cervix.
31. A light source for therapy or diagnosis, comprising an array of light emitting diodes coupled to light guiding means for delivering light emitted by the diodes to an area to be treated.
- 30

32. A light source as claimed in claim 31, wherein at least part of the light guiding means is tapered away from the diodes.
- 5 33. A light source as claimed in claim 32, wherein the light guiding means includes a tapered part which tapers away from the diodes so as to concentrate the light emitted by the diodes into a parallel-sided light guide.
- 10 34. A light source as claimed in claim 31, wherein the light emitting diodes are integrated in the array.
35. A light source as claimed in claim 34, wherein the diodes are thermally coupled to thermoelectric cooling means.
- 15 36. A light source as claimed in claim 34 or 35, wherein the light guiding means comprises a parallel-sided light guide coupled to the integrated array.
- 20 37. A light source as claimed in claim 33 or 36, wherein the parallel-sided light guide comprises one or more optical fibres and/or liquid light guides.
- 25 38. A light source for therapy or diagnosis, comprising an array of light emitting diodes having emission wavelengths substantially within the range 550 to 660 nm.
- 30 39. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 590 to 640 nm.

40. A light source as claimed in claim 39, wherein the diodes are of aluminium indium gallium phosphide/gallium phosphide die material.
- 5 41. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 560 to 644 nm.
42. A light source as claimed in claim 41, wherein the diodes are of aluminium indium gallium phosphide/gallium arsenic die material.
- 10 43. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 650 to 660 nm.
44. A light source as claimed in claim 43, wherein the diodes are of aluminium gallium arsenic die material.
- 15 45. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 550 to 570 nm.
- 20 46. A light source as claimed in claim 45, wherein the diodes are of gallium phosphide die material.
47. A light source for therapy or diagnosis, comprising an array of LED's with peak emission spectra of approximately 470 nm, 505 nm or 525 nm.
- 25 48. A light source as claimed in claim 47, wherein the diodes are of indium gallium nitride die material.

49. A therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm.
50. A light source as claimed in claim 49, wherein the diodes are of gallium nitride/silicon die material.
51. A light source as claimed in any of claims 10 to 50, wherein said LED's include a first set of LED's and a second set of LED's having different emission spectra from said first set.
52. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second set of LED's having different emission spectra from said first set.
53. A light source as claimed in claim 52, wherein the first and second set of LED's are independently switchable.
54. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second, spatially distinct set of LED's independently switchable from said first set.
55. Use of a light source as claimed in any one of claims 10 to 50 except for claims 29 and 30, and claims dependent thereon, for cosmetic treatment of a patient.
56. Use as claimed in claim 55, for photodynamic treatment of the patient.
57. Use as claimed in claim 56, for portwine stain removal, or hair restoration or removal.

58. Use as claimed in claim 55, for skin rejuvenation, wrinkle removal or biostimulation.
- 5 59. Use of a light source as claimed in any one of claims 10 to 54, for medical treatment of a patient.
60. Use as claimed in claim 59, for photodynamic treatment of a patient.
- 10 61. Use as claimed in claim 60, except when dependent on claim 29 or 30, in the treatment of one or more of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas),
- 15 viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism.
- 20 62. A light source for therapy or diagnosis substantially as herein described with reference to and/or as shown in Figures 1 to 4, or Figure 5, or Figure 6, or Figure 7, or Figure 8, or Figure 9, or Figures 10a and 10b, or Figures 11a to 11c, or Figure 12, or Figure 13, or Figure 14, or Figure 15, or Figures 16a and 16b, or Figures 17a and 17b, or Figures 18a and 18b, or Figures 19a and 19b, or
- 25 Figures 20a and 20b, or Figure 21, or Figures 22a to 22c, or
- 30

Figures 23a to 23c, or Figure 24, or Figure 25, or Figure 26 of the accompanying drawings.



INVESTOR IN PEOPLE

Application No: GB 0030974.0

Examiner: Susan Chalmers  
(Mrs)

Claims searched: 1-10

Date of search: 24 May 2001

**Patents Act 1977**  
**Search Report under Section 17****Databases searched:**

UK Patent Office collections, including GB, EP, WO &amp; US patent specifications, in:

UK Cl (Ed.S): A5R: REHR

Int Cl (Ed.7): A61N: 5/06

Other: ONLINE: EPODOC, WPI, JAPIO

**Documents considered to be relevant:**

Category	Identity of document and relevant passage		Relevant to claims
E,X	WO 01/14012 A	(RUSSELL) see Figures, page 5 line 24 to page 6 line 9, page 21 line 20 to page 22 line 29 and page 24 line 1 to page 25 line 12	1,2 at least
P,Y	WO 00/15296 A	(LIGHT SCIENCES) see eg Figures 5-8, page 2 line 31 to page 3 line 9 and page 8 line 3 to page 10 line 6	1-9
X	WO 99/19024 A	(VIRULITE) see Figures 13 and 14 and page 8 lines 15-20	1,2 at least
X	WO 98/43703 A	(PRESCOTT) see especially page 5 lines 16-26, page 9 lines 16-26 and page 18 lines 4-25	1,2 at least
Y	EP 0266038 A	(KUREHA) see photodiodes 3a,3b in Figures 1-3 and page 3 lines 32-40	1,3-5
X	US 5616140	(PRESCOTT) see parts 20,22,702,802 in the Figures, column 5 lines 1-10 and 54-62 and column 14 line 64 to page 15 line 9	1,2,5-9 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.



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**F4R RPM R288 R330 R333**

(56) Documents Cited  
**WO 98/52645 A1 WO 97/14915 A1 DD 000257200 A**  
**JP 580049435 A JP 560155765 A**  
**WPI Abstract Accession No. 1988-293599/42 &**  
**DD257200A**

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UK CL (Edition S ) **A5R REHR , F4R RPM R288 R330**  
**R333**  
INT CL<sup>7</sup> **A61N 5/00 5/01 5/06 , F21V 29/00**  
Online: EPODOC, WPI, PAJ

(54) Abstract Title  
**Dermatological treatment apparatus**

(57) Dermatological treatment apparatus for treating human skin with intense visible light is disclosed. The apparatus has a light source 40 within a cooling fluid duct 42, the cooling fluid duct 42 having a light transmissive region and a light reflective region disposed to reflect light from the light source through the light transmissive region. The light reflective region may be formed by a coating 54 applied to a region of the cooling fluid duct 42. Such a coating may, in preferred embodiments, include a reflective metal layer, and one or more additional layers. The light source may be flash lamp such as a xenon discharge tube. A control unit is typically included to provide controlled power to the light source.

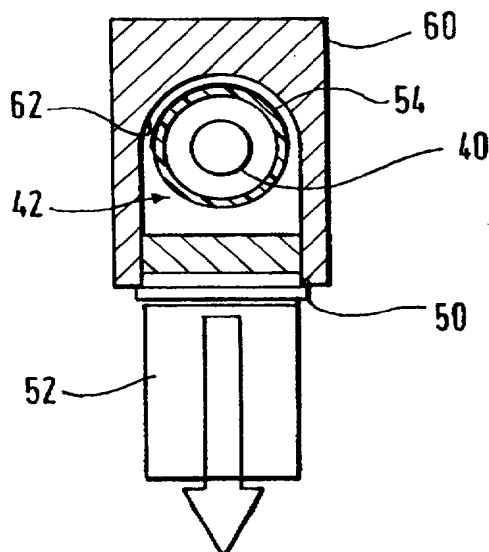


FIG.3.

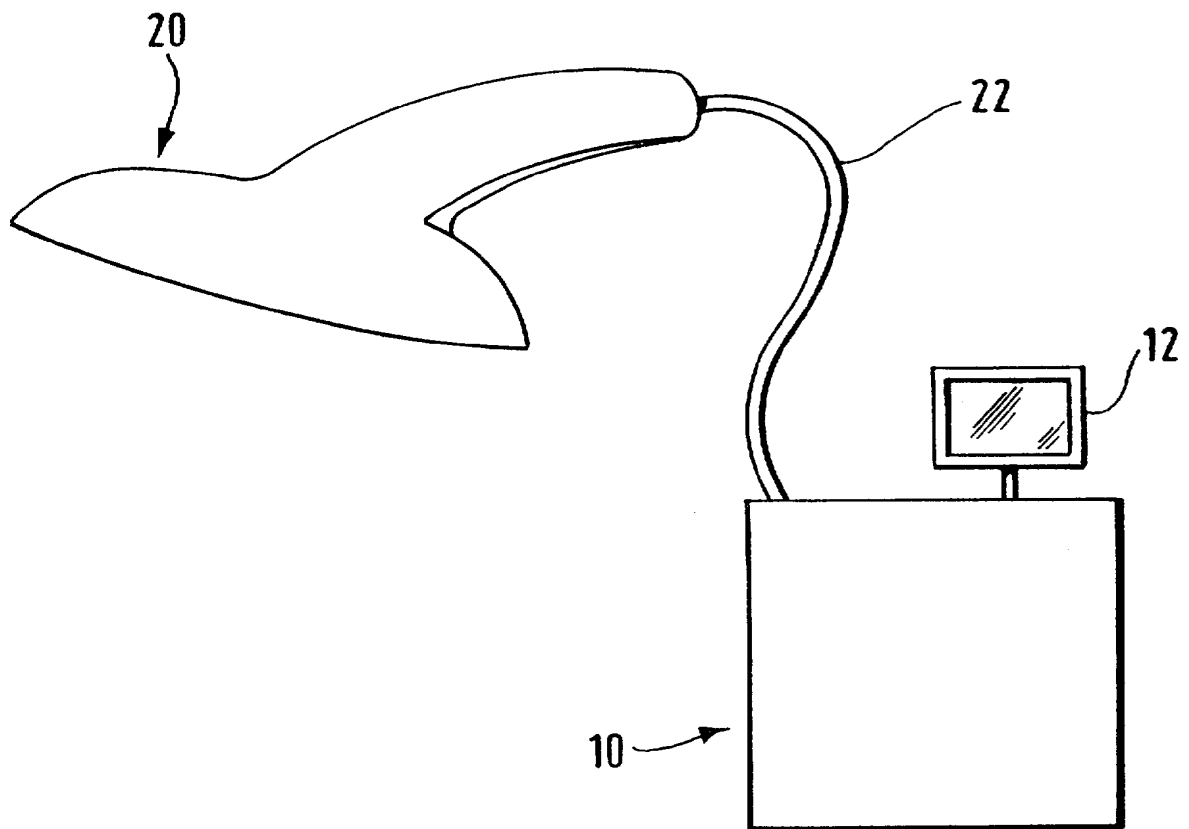


FIG.1.

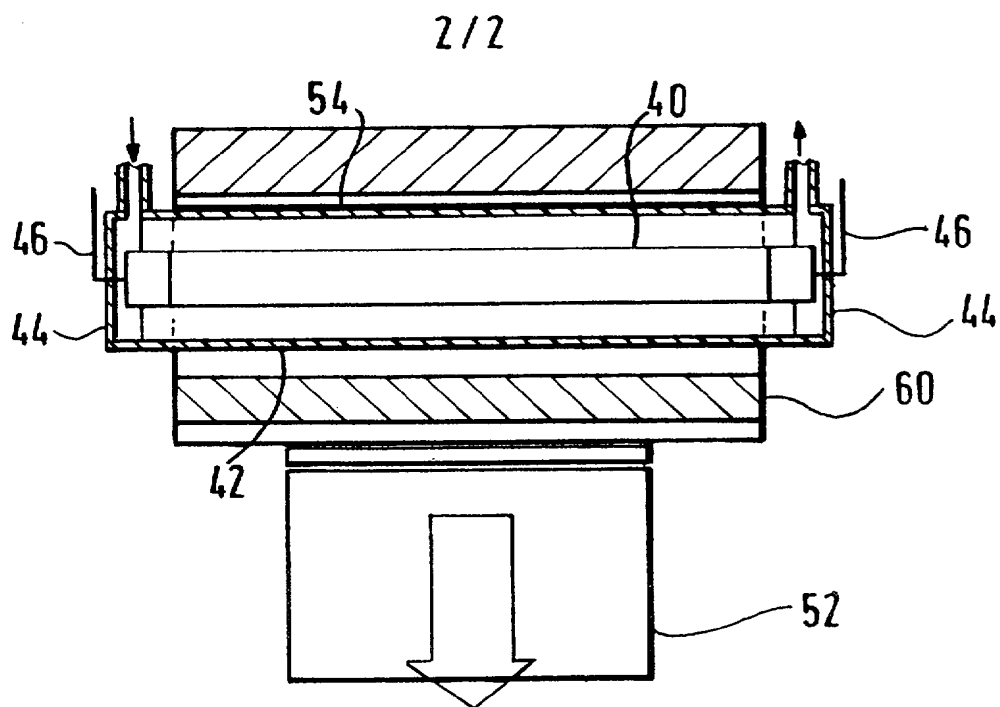


FIG. 2.

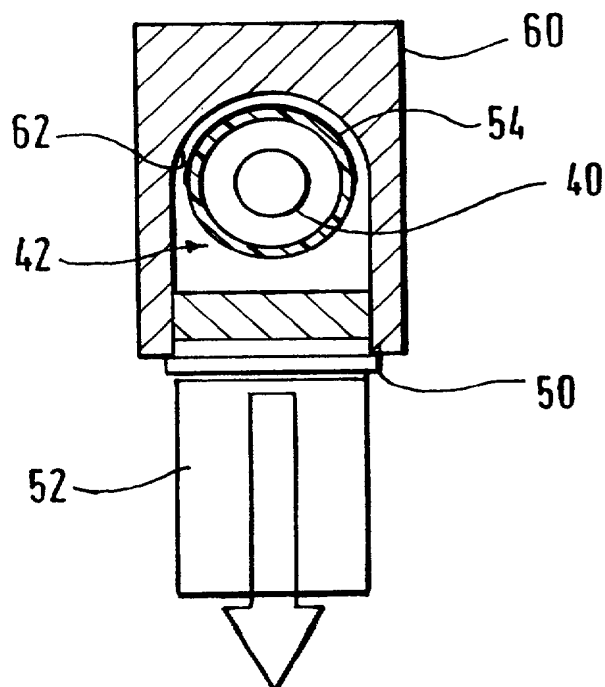


FIG. 3.

### **Dermatological treatment apparatus**

The present invention relates to dermatological treatment apparatus. In particular, this invention relates to apparatus for treating human skin using visible light.

5 It is known to treat conditions and perform cosmetic treatment of human skin using high-intensity visible light. For example, it is well known to erase tattoos and other skin pigmentation and to remove unwanted hair by application of high-intensity light to the skin.

10 One form of this treatment uses laser light. This can provide light that can be accurately directed and controlled by a practitioner to provide effective treatment. However, laser apparatus for carrying out such treatment is typically costly and, in many cases, requires a dedicated power supply; two issues that limit the availability of the apparatus and hence restrict access to the treatment that requires such apparatus.

15 An alternative type of apparatus is also known that uses high-intensity non-laser light, for example, as generated by a discharge tube. Unlike a laser, a discharge tube emits light in a wide range of directions, so the apparatus must typically be provided with a light control arrangement to direct light emitted from the tube towards a treatment site. In known apparatus, the light control arrangement may include a highly polished metal reflector. A disadvantage of this type of apparatus is that the tube emits a large amount of heat. For this reason, the discharge tube is typically disposed within a duct that  
20 carries a flow of cooling fluid, for example, deionised water. While this assists in removing heat from the apparatus, it can reduce the efficiency with which light can be reflected by the reflector so reducing the amount of light produced by the apparatus. Moreover, a substantial amount of heat may nevertheless be transferred from the discharge tube into the reflector, and, in turn, into components connected to the  
25 reflector. This can be especially disadvantageous where the apparatus is to be hand held by a practitioner, to whom the heat can cause discomfort over time.

An aim of this invention is to provide dermatological treatment apparatus of the general type described in the last-preceding paragraph that avoids or at least ameliorates disadvantages of known apparatus.

5 From a first aspect, the invention provides dermatological treatment apparatus having a light source within a cooling fluid flow duct, the cooling fluid duct having a light transmissive region and a light reflective region disposed to reflect light from the light source through the light transmissive region.

10 This arrangement provides a reflector that is straightforward to produce, that is compact, and that is efficient. In particular, it avoids the need to manufacture, and can omit the weight of, a separate reflector, which, in known systems, is typically formed from a highly polished metal body. Moreover, it ensures that the amount of heat that can escape from the cooling fluid duct into surrounding components is minimised, so restricting the amount of heat that can be passed to other components within the treatment head.

15 The cooling fluid duct is typically formed from a hard, heat-resistant, transparent material. For example, it may be glass. It might alternatively be quartz, a material that can be more resistant to heat. It typically has a tubular section. For example, it may be cylindrical, this being the simplest shape to produce. Alternatively, the cooling fluid duct may have a cross-sectional shape selected to confer advantageous optical  
20 properties upon the reflective region. For example, the cooling fluid duct may have a cross-section that is in part approximately or substantially parabolic to focus light emitted by the light source.

The light reflective region is typically constituted by a region of the cooling fluid flow duct coated with a reflective coating. The reflective coating may include a reflecting  
25 layer of metal, such as silver, aluminium, or a mixture of those and/or other metals. Such a reflective layer can readily be formed by various techniques, including, for example, vacuum deposition. The reflective coating may include one or more layers in addition to the reflecting layer. Such additional layers may, for example, contribute to

properties of the reflective coating. Those properties may include the physical robustness, the reflectiveness, the opacity, and/or the ability to disperse heat. For example, the additional layers may include a layer of paint to protect underlying reflective layers.

- 5 As a specific example, the reflective coating may comprise a layer of silver metal deposited upon the material of the cooling fluid duct, a layer of copper deposited upon the layer of silver, and a protective paint layer applied to the copper layer. Alternatively, the layer of copper may be omitted.

10 From a second aspect, the invention provides a dermatological treatment unit comprising apparatus according to the first aspect of the invention contained within a treatment head, and a control unit for controlling operation of the apparatus. In such a unit, the control unit may be connected to the treatment head by a cable through which electrical signals and/or cooling fluid is conveyed.

15 An embodiment of the invention will now be described in detail, by way of example, and with reference to the accompanying drawings, in which:

Figure 1 is an external view (not to scale) of a treatment head and a controller, being components of treatment apparatus embodying the invention; and

Figures 2 and 3 are diagrammatic side and end views of a discharge tube and associated components in apparatus embodying the invention.

20 With reference to the drawings, dermatological treatment apparatus embodying the invention includes a control unit 10 that contains electronic control components responsible for operation of the apparatus. The control unit 10 also has a user control panel 12 whereby an operator can control operation of the apparatus. A control unit of substantially convention construction may be suitable for use in embodiments of the  
25 invention. The construction of such a conventional control unit 10 is well understood by those skilled in the relevant technical fields, and will not therefore be described further.

A treatment head 20 is connected to the control unit 10 by a connecting cable 22. The treatment head 20 is a unit that can be hand held by an operator to apply pulses of high-intensity visible light to a specific treatment site on a patient's skin, for example, in treatment for removal of unwanted hair. As will be appreciated, the requirement for the treatment head to be hand held places a restriction upon the design of the treatment head 20 in terms of its maximum weight, maximum operating temperature, and many other requirements. The present invention is intended to assist in the design of a treatment head that has an advantageously low operating temperature, and can minimise weight. Most other of these requirements are not central to this invention, and will therefore not be discussed further.

Internal components of the treatment head 20 most relevant to the invention will now be described.

The treatment head 20 includes a flash tube 40. In this example, the flash tube is a xenon discharge lamp, capable of producing a train of high-intensity pulses of light of short duration. In this embodiment, the flash tube 40 is an elongate linear tube. The flash tube 40 is provided with a suitable supply of electrical power generated by the control unit 10 and carried to the treatment head 20 by the cable 22 in a manner well understood by those skilled in the technical field.

The flash tube 40 is disposed within a cooling fluid duct 42. The cooling fluid duct 42 is formed as a cylinder of transparent heat-resistant material such as borosilicate or cerium-doped quartz. During operation of the apparatus, a flow of cooling water is pumped through the length of the cooling fluid duct 42 to carry heat away from the flash tube 40. Deionised water may suitably be used as a cooling fluid. The cooling water is conveyed in a continuous circuit to and from the cooling fluid duct 42 by conduits 44 that connect it to the cable 22 and thence to a pump and to a heat exchanger contained within the control unit 10. Power supply lines 46 for the flash tube 40 are conveyed through suitable sealed apertures in the conduits 46.

Light emitted from the flash tube 40 is directed to the reflector through the filter element 50 and from there conveyed by a light guide 52 to an outlet window (not shown) of the treatment head 20. For use, the outlet window is placed in contact with an area of skin that is to be subjected to treatment.

- 5 In order to guide light emitted from the flash tube 40 towards the filter element 50, a reflective coating 54 is applied to a region of an outer wall of the cooling fluid duct 42. Light that is produced within the flash tube 40 may strike the reflective coating 54 to be reflected in a direction generally towards the light guide 52. The region upon which the coating is applied extends to such a length that it lies adjacent to the flash tube 40 along
- 10 substantially the entire length that the flash tube 40 emits light. The reflective coating 54 extends around the duct to cover somewhat more than half of the extent of the duct 42; that is to say, when viewed from an end of the tube, the reflective coating 54 extends around the tube by an angle somewhat greater than  $180^\circ$ . The particular angle of coverage of the reflective coating 54 is selected to maximise the amount of light
- 15 transferred from the flash tube 40 to the light guide 52. The precise angle is determined by the arrangement of a specific embodiment, and may be selected by experiment.

- In this example, the reflective coating 54 includes several layers. A first layer is a reflective layer and is formed in direct contact with an external surface of the cooling fluid duct 42. The reflective layer is a layer of deposited metal, for example, silver
- 20 metal, aluminium metal, or a mixture of those and/or other bright metals. The reflective layer is formed by vacuum deposition of metal ions onto the surface of the cooling fluid duct 42. As will be appreciated, the shape of the reflective layer, and therefore its optical performance, is determined by the external shape of the cooling fluid duct 42.
- 25 This shape is selected to confer upon the reflective layer a shape suitable for optimising the transfer of light emitted by the flash tube 40 towards the light guide 52. Such a construction can provide a reflector of good optical performance with a minimum of cost and complication in manufacture.

A second layer is applied to cover the reflective layer. In this example, the second layer is a deposited layer of copper metal. On top of these metal layers, a protective coating



of paint is applied to provide protection to the reflective metal layers below. In a proposed alternative embodiment, the copper metal layer is omitted from the reflective coating 54.

5 The cooling fluid duct 42 and the flash tube 40 are carried within a metal (for example, aluminium) block 60 that serves to maintain all of the components in a fixed relationship to one another. Other components of the treatment head not shown in the drawings may also be carried on the block 60. A U-shaped slot 62 is formed in the block 60 to enclose the cooling fluid duct 42 and the flash tube 40 within. At its base, the slot 62 may optionally be shaped and/or polished to gather light that is not reflected  
10 by the reflective coating 54 and to direct that light towards the light guide 52. Cooling fluid ducts may be provided within the block 60 to carry a circulation of cooling water to remove heat from the block.

It will be understood that much of the radiant heat emitted by the flash tube 40 will be reflected by the reflective coating 54 and will therefore not escape the cooling duct to  
15 reach the block 60 or other components of the treatment head 20. This ensures that a treatment head 20 of apparatus embodying the invention is inherently less prone to become hot than is the case in conventional apparatus in which reflection is principally achieved by, for example, a highly polished region of the block 60.

20 It will be understood that the embodiment described above is presented by way of example only, and does not limit the scope of the invention. Moreover, each feature is disclosed in the description, the claims and the drawings may be provided independently or in any appropriate combination.

**Claims.**

1. Dermatological treatment apparatus having a light source within a cooling fluid flow duct, the cooling fluid duct having a light transmissive region and a light reflective region disposed to reflect light from the light source through the light transmissive region.  
5
2. Dermatological treatment apparatus according to claim 1 in which the cooling fluid duct is formed from a hard, heat-resistant, transparent material.
3. Dermatological treatment apparatus according to claim 2 in which the fluid duct is formed of glass.
- 10 4. Dermatological treatment apparatus according to claim 2 in which the fluid duct is formed of quartz.
5. Dermatological treatment apparatus according to any preceding claim in which the cooling fluid duct has a tubular section.
6. Dermatological treatment apparatus according to claim 5 in which the cooling fluid duct is generally cylindrical.  
15
7. Dermatological treatment apparatus according to any one of claims 1 to 5 in which the cooling fluid duct has a cross-sectional shape selected to confer advantageous optical properties upon the reflective region.
8. Dermatological treatment apparatus according to claim 7 in which the cooling fluid duct has a cross-section that is in part approximately parabolic.  
20
9. Dermatological treatment apparatus according to any preceding claim in which the light reflective region is constituted by a region of the cooling fluid flow duct coated with a reflective coating.

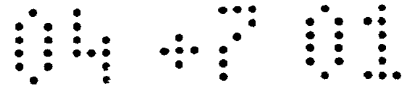
10. Dermatological treatment apparatus according to claim 9 in which the reflective coating includes a reflecting layer of reflective metal, such as silver, aluminium, or mixture of those and/or other metals.
- 5 11. Dermatological treatment apparatus according to claim 9 or claim 10 in which the reflective coating includes one or more layers in addition to the said reflecting layer.
- 10 12. Dermatological treatment apparatus according to claim 11 in which such additional layers contribute to properties of the reflective coating, the properties including any or all of its physical robustness, its reflectiveness, its opacity, and/or its ability to disperse heat.
13. Dermatological treatment apparatus according to claim 12 in which the additional layers include a layer of paint that serves to protect underlying reflective layers.
- 15 14. Dermatological treatment apparatus according to claim 9 in which the reflective coating comprises a layer of silver metal deposited upon the material of the cooling fluid duct, a layer of copper deposited upon the layer of silver, and a protective paint layer applied to the copper layer.
- 20 15. Dermatological treatment apparatus according to claim 9 in which the reflective coating comprises a layer of silver metal deposited upon the material of the cooling fluid duct, and a protective paint layer applied to the silver layer.
16. Dermatological treatment apparatus according to any preceding claim in which the cooling fluid is water.
17. Dermatological treatment apparatus substantially as herein described with reference to the accompanying drawings.

18. A dermatological treatment unit comprising apparatus according to any preceding claim contained within a treatment head, and a control unit for controlling operation of the apparatus.
- 5 19. A dermatological treatment unit according to claim 16 in which the control unit is connected to the treatment head by a cable through which electrical signals and/or cooling fluid is conveyed.
20. A dermatological treatment unit substantially as herein described with reference to the accompanying drawings.

**Amendments to the claims have been filed as follows***10***Claims.**

1. Dermatological treatment apparatus having a light source within a cooling fluid flow duct that contains cooling fluid in contact with the light source, the cooling fluid duct having a light transmissive region and a light reflective region disposed to reflect light from the light source through the light transmissive region to be received by a light guide.  
5
2. Dermatological treatment apparatus according to claim 1 in which the cooling fluid duct is formed from a hard, heat-resistant, transparent material.
3. Dermatological treatment apparatus according to claim 2 in which the fluid duct is formed of glass.  
10
4. Dermatological treatment apparatus according to claim 2 in which the fluid duct is formed of quartz.
5. Dermatological treatment apparatus according to any preceding claim in which the cooling fluid duct has a tubular section.
- 15 6. Dermatological treatment apparatus according to claim 5 in which the cooling fluid duct is generally cylindrical.
7. Dermatological treatment apparatus according to any one of claims 1 to 5 in which the cooling fluid duct has a cross-sectional shape selected to confer advantageous optical properties upon the reflective region.
- 20 8. Dermatological treatment apparatus according to claim 7 in which the cooling fluid duct has a cross-section that is in part approximately parabolic.

9. Dermatological treatment apparatus according to any preceding claim in which the light reflective region is constituted by a region of the cooling fluid flow duct coated with a reflective coating.
10. Dermatological treatment apparatus according to claim 9 in which the reflective coating includes a reflecting layer of reflective metal, such as silver, aluminium, or mixture of those and/or other metals.
11. Dermatological treatment apparatus according to claim 9 or claim 10 in which the reflective coating includes one or more layers in addition to the said reflecting layer.
12. Dermatological treatment apparatus according to claim 11 in which such additional layers contribute to properties of the reflective coating, the properties including any or all of its physical robustness, its reflectiveness, its opacity, and/or its ability to disperse heat.
13. Dermatological treatment apparatus according to claim 12 in which the additional layers include a layer of paint that serves to protect underlying reflective layers.
14. Dermatological treatment apparatus according to claim 9 in which the reflective coating comprises a layer of silver metal deposited upon the material of the cooling fluid duct, a layer of copper deposited upon the layer of silver, and a protective paint layer applied to the copper layer.
15. Dermatological treatment apparatus according to claim 9 in which the reflective coating comprises a layer of silver metal deposited upon the material of the cooling fluid duct, and a protective paint layer applied to the silver layer.
16. Dermatological treatment apparatus according to any preceding claim in which the cooling fluid is water.



17. Dermatological treatment apparatus substantially as herein described with reference to the accompanying drawings.
18. A dermatological treatment unit comprising apparatus according to any preceding claim contained within a treatment head, and a control unit for  
5 controlling operation of the apparatus.
19. A dermatological treatment unit according to claim 18 in which the control unit is connected to the treatment head by a cable through which electrical signals and/or cooling fluid is conveyed.
20. A dermatological treatment unit substantially as herein described with reference  
10 to the accompanying drawings.



INVESTOR IN PEOPLE

**Application No:** GB 0008624.9  
**Claims searched:** 1-20

**Examiner:** Dr Jeremy Kaye  
**Date of search:** 19 March 2001

## Patents Act 1977 Search Report under Section 17

### Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:  
 UK CI (Ed.S): A5R (REHR); F4R (RPM)  
 Int CI (Ed.7): A61N 5/00, 5/01, 5/06; F21V 29/00  
 Other: Online: EPODOC, WPI, PAJ

### Documents considered to be relevant:

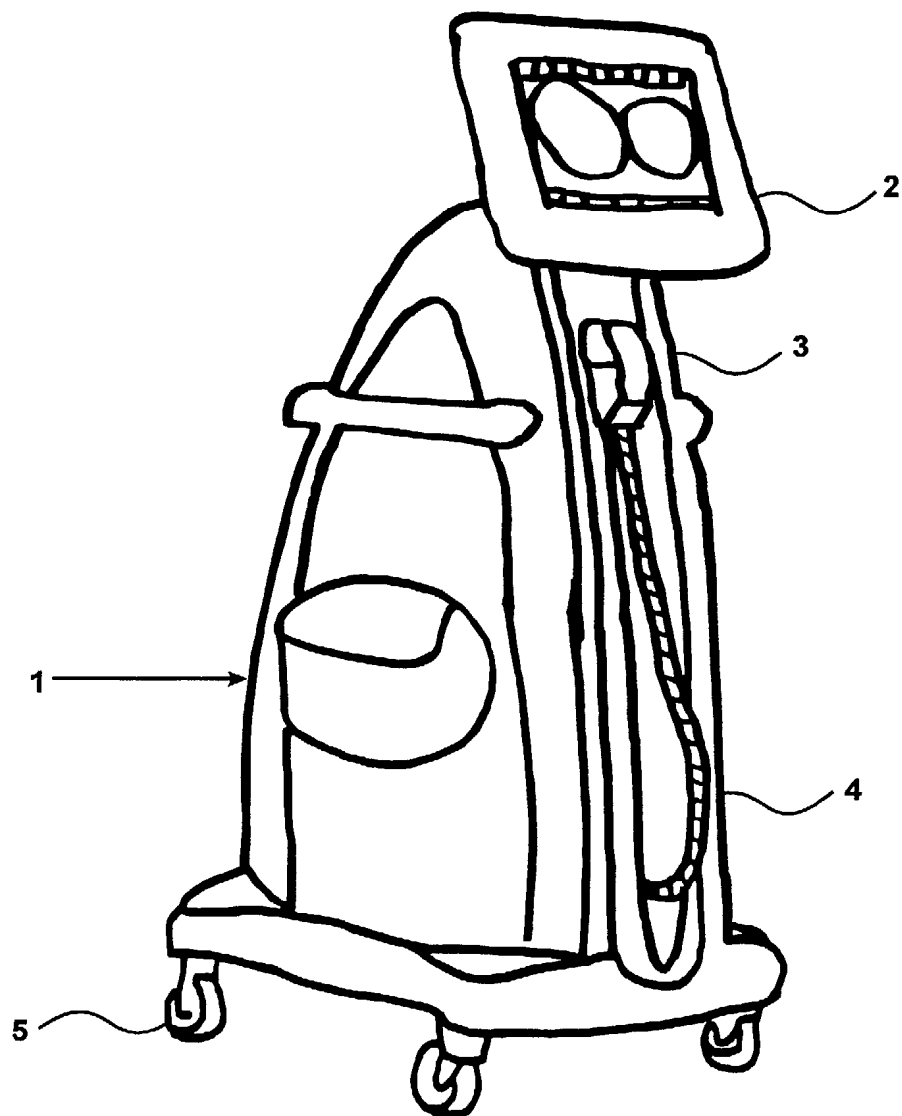
Category	Identity of document and relevant passage	Relevant to claims
X	WO 98/52645 A1 (GUSTAFSSON) p.2, ll.1-31; p.5, l.17 - p.6, l.27; p.8, ll.5-17; p.9, l.19 - p.11, l.1; figures 1 and 2.	1-6, 9-11, 16, 18, 19
X	WO 97/14915 A1 (THE REGENTS OF U. CAL) p.5, ll.3-9; p.6, ll.3-10; figures 1, 2 and 3.	1, 5, 6, 16, 19
X	JP 58049435 (TOSHIBA) see PAJ abstract and figure	1
X	JP 56155765 (USHIO) see PAJ abstract and figure	1
X	DD 257200 A (HECHT ET AL.) see abstract	1
A	WPI Abstract Accession No. 1997-364353/34 & CN 1108959A (HAO) (see abstract).	1

X Document indicating lack of novelty or inventive step  
 Y Document indicating lack of inventive step if combined with one or more other documents of same category.  
 & Member of the same patent family

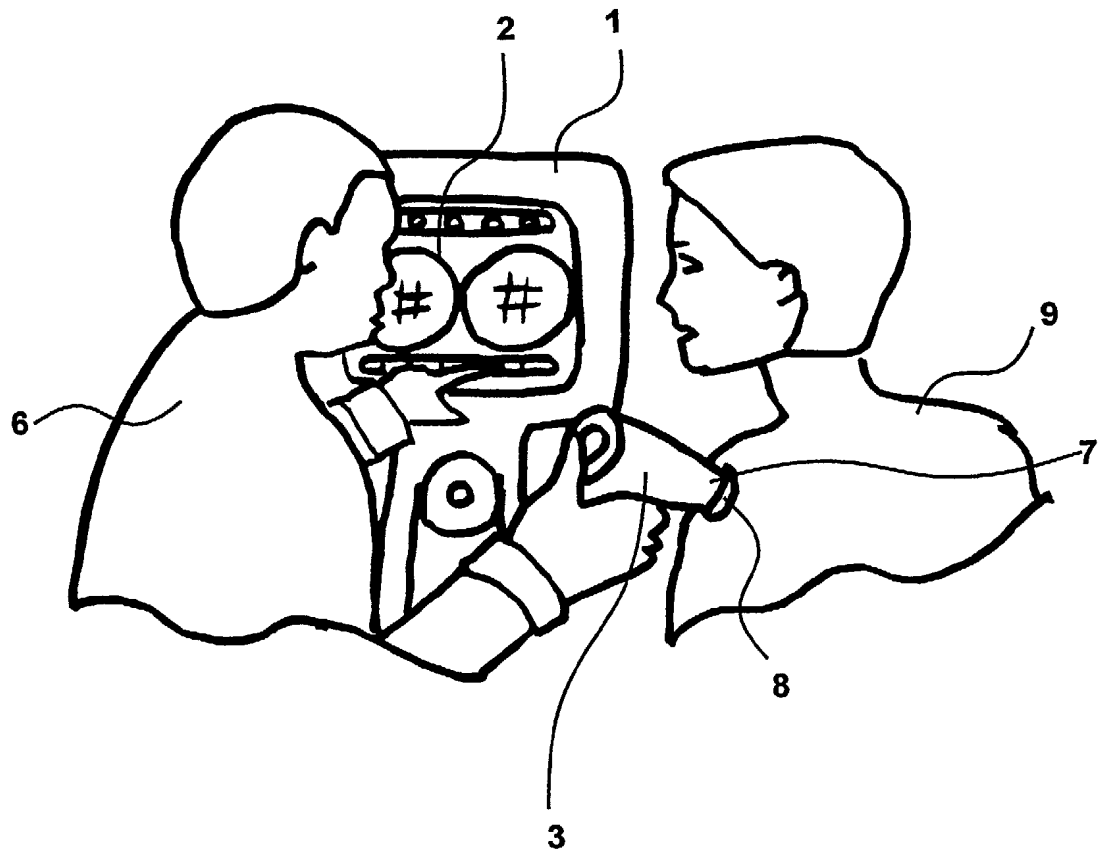
A Document indicating technological background and/or state of the art.  
 P Document published on or after the declared priority date but before the filing date of this invention.  
 E Patent document published on or after, but with priority date earlier than, the filing date of this application.



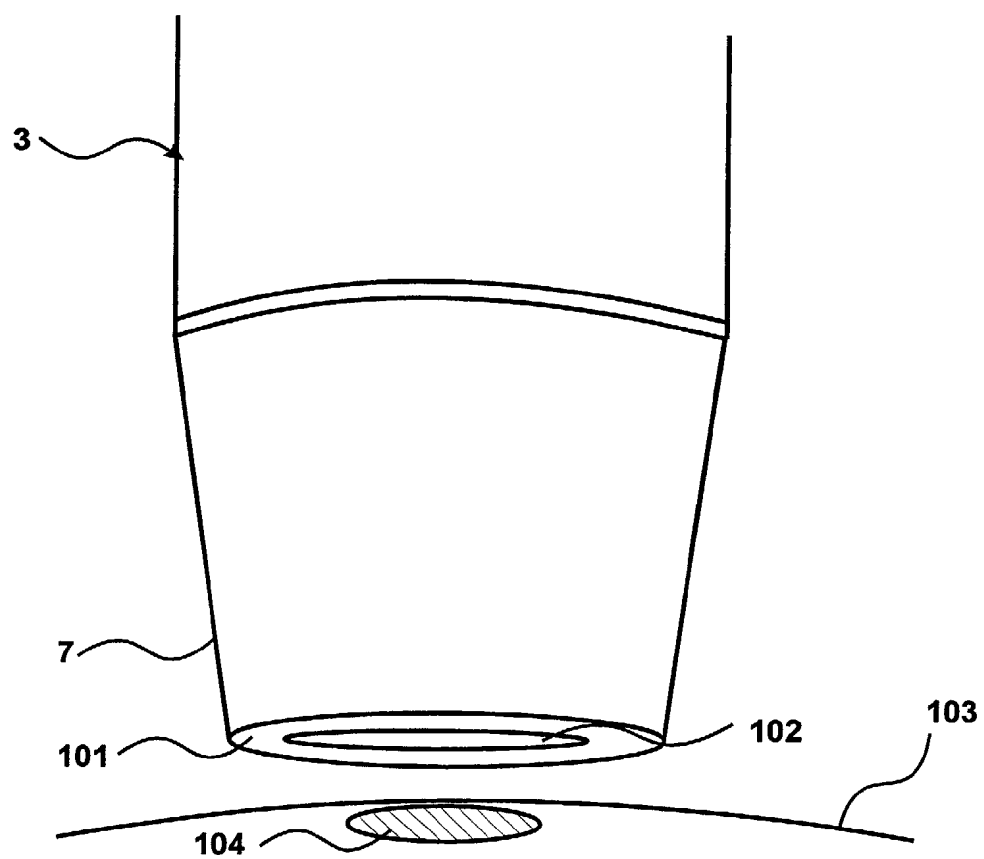




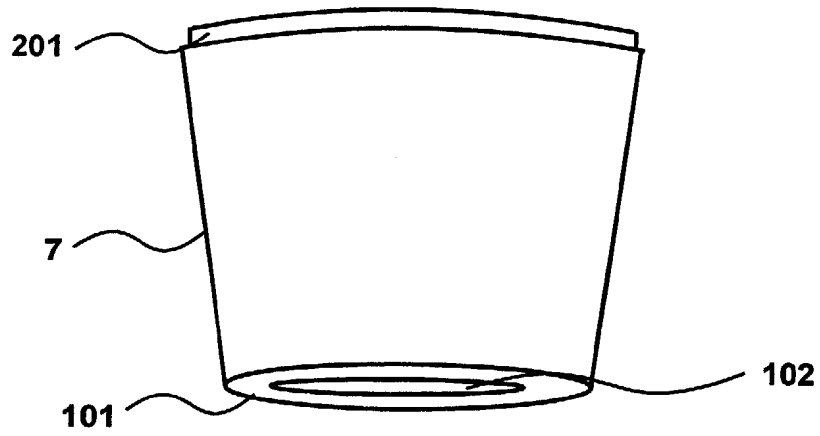
*Figure A*



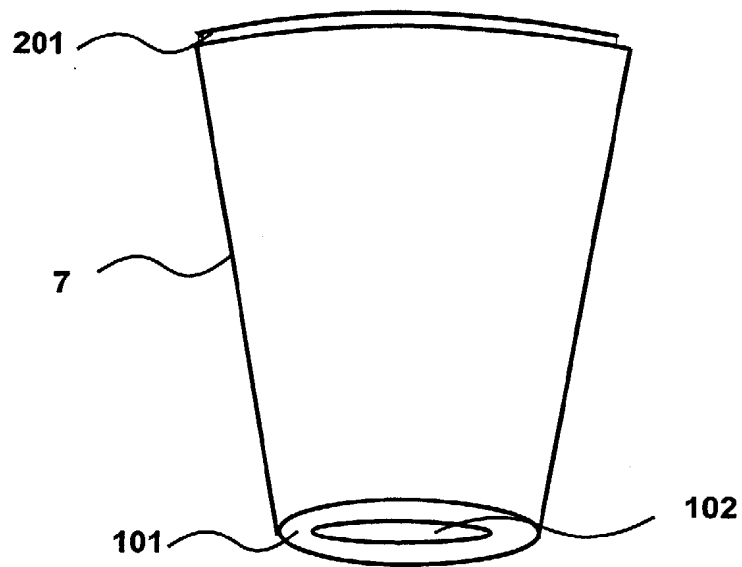
*Figure B*



*Figure 1*



*Figure 2a*



*Figure 2b*

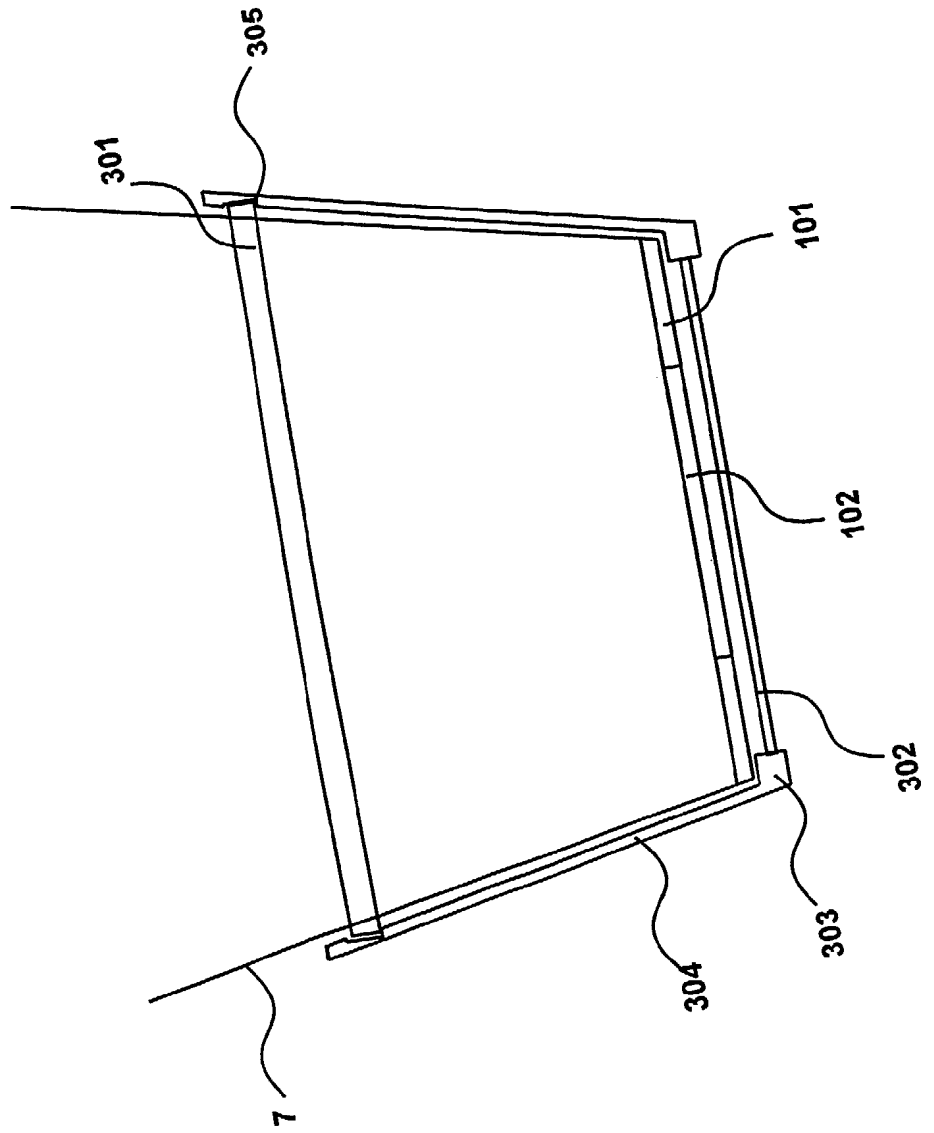
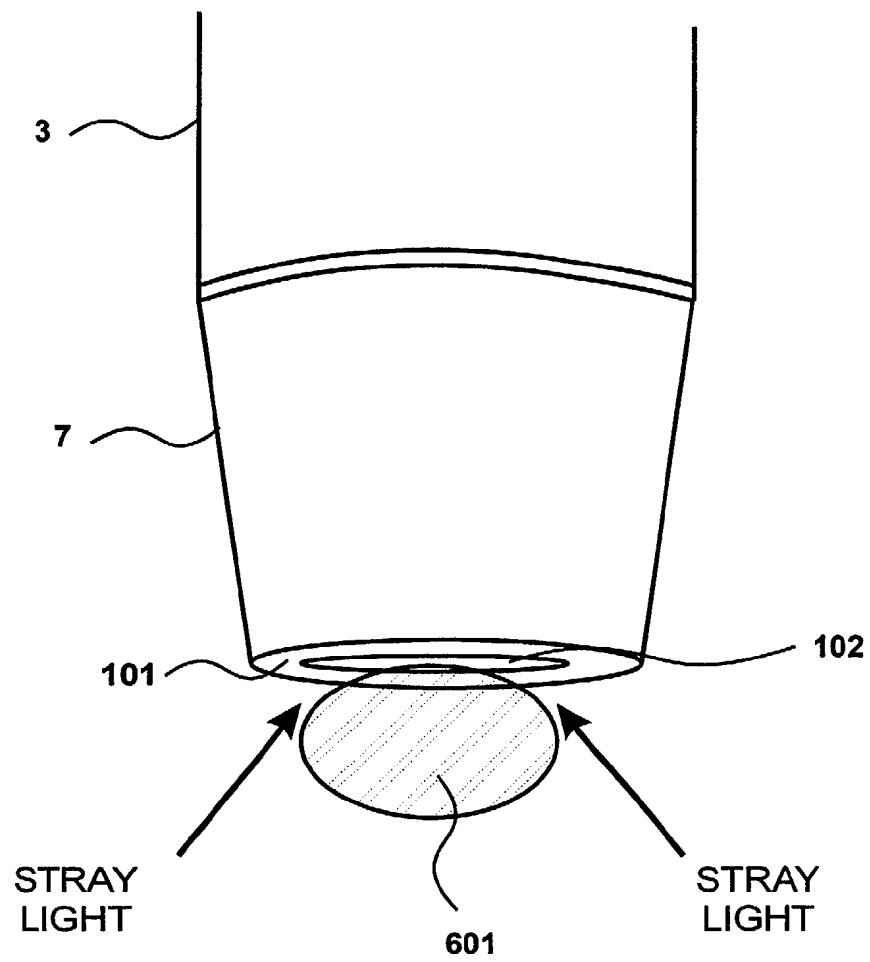


Figure 3

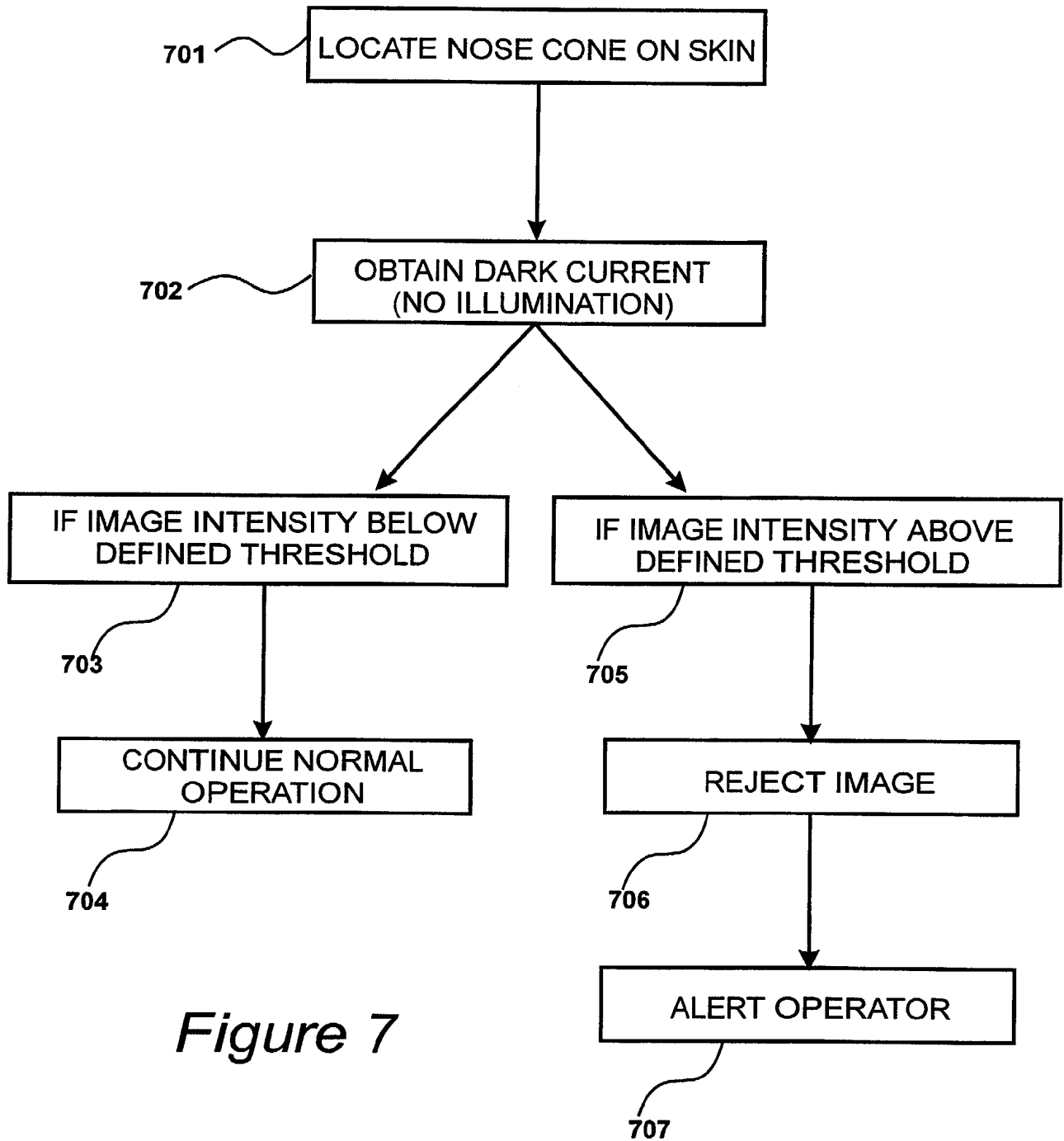
A cross-sectional view of a curved structure, likely a portion of a lens or a similar optical component. The structure is shown in a curved, elongated shape. It features a central layer, labeled 401, which is filled with diagonal hatching. This central layer is flanked by two outer layers, both labeled 403. The entire structure is bounded by a top surface, labeled 302, which is a smooth, continuous curve. The bottom surface is also curved, following the outer contour of the hatched layer 401.

*Figure 5*

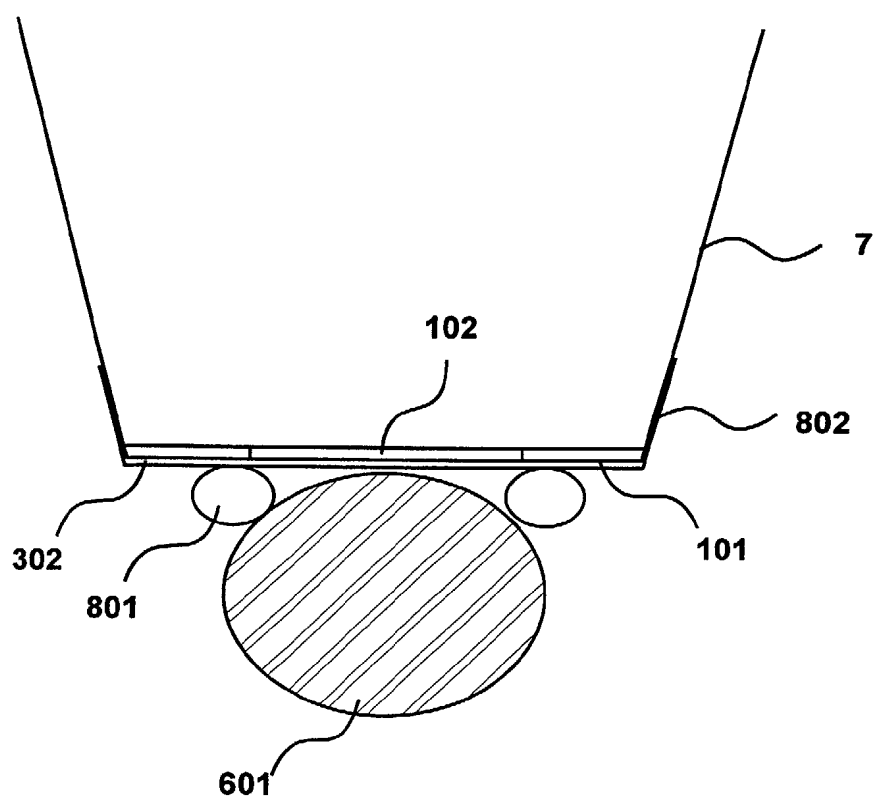


*Figure 6*



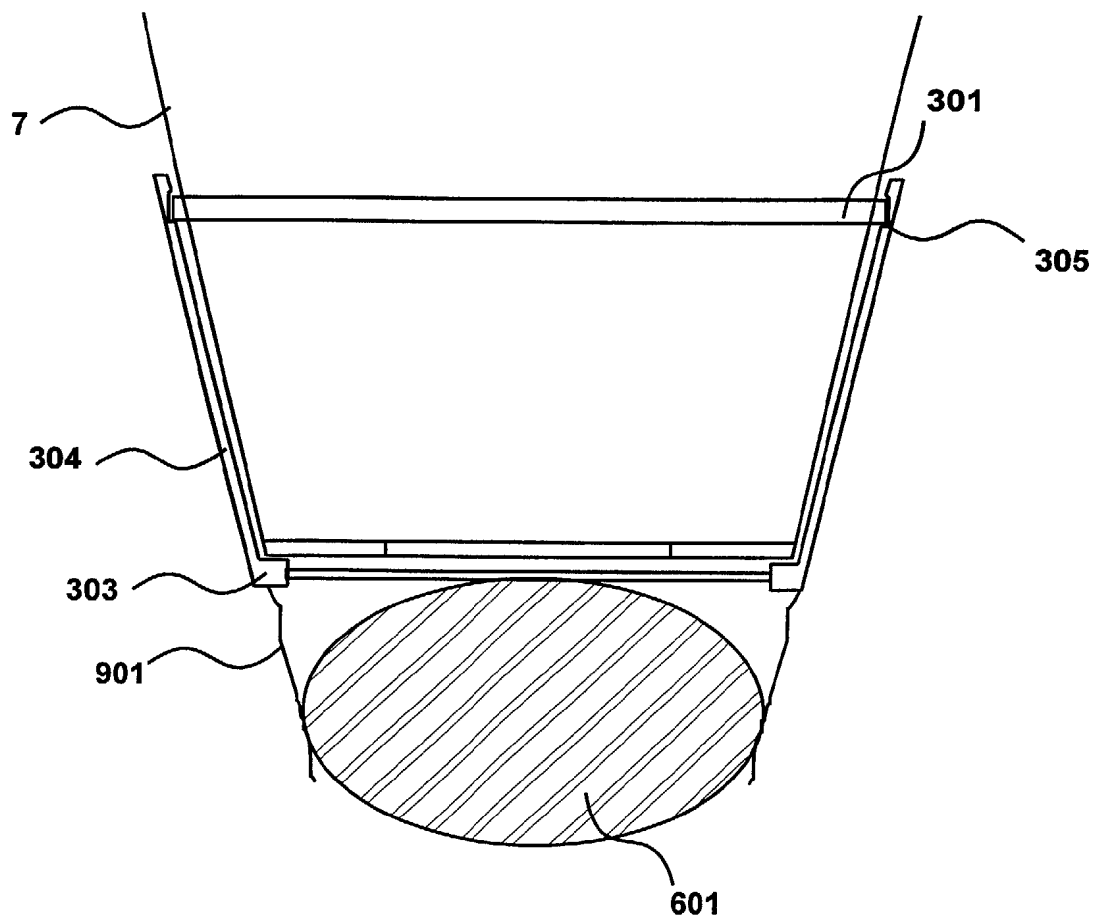
*Figure 7*

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*Figure 8*

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*Figure 9*

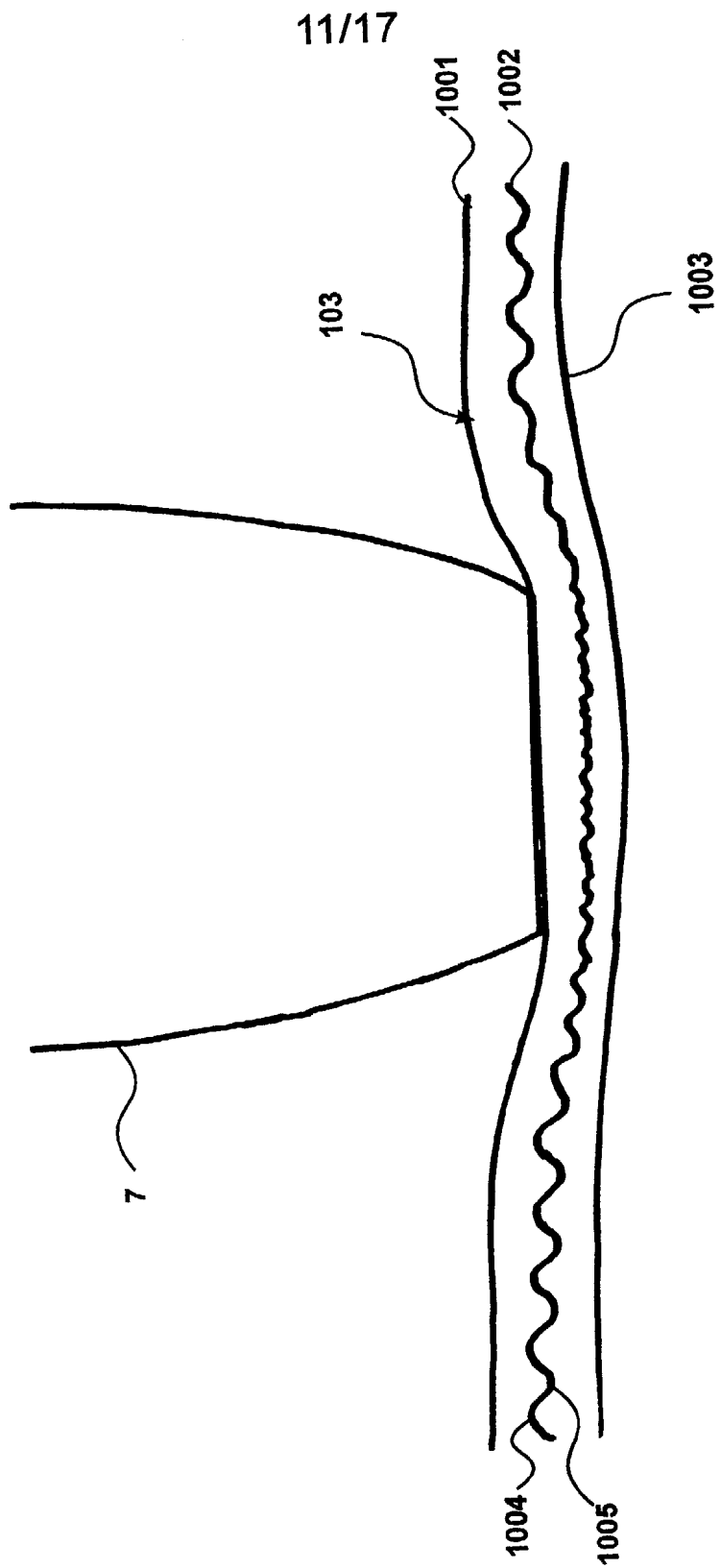
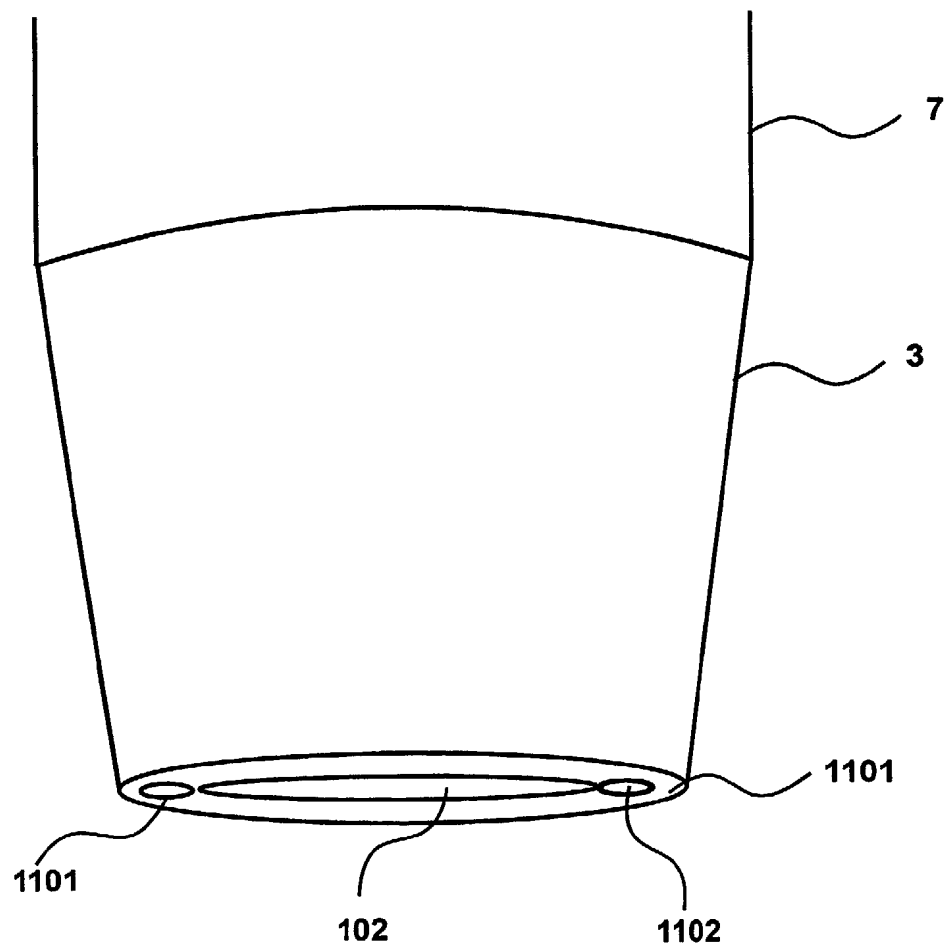
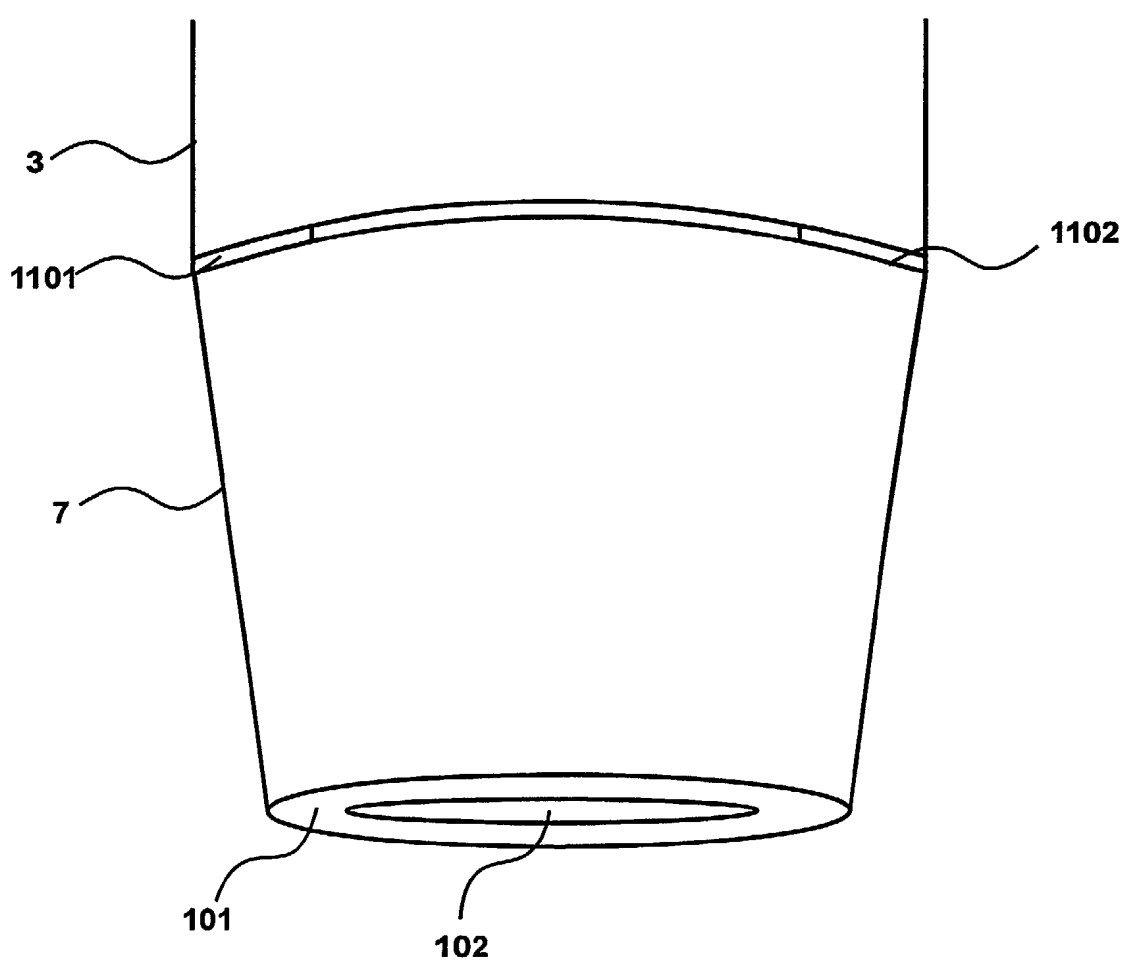


Figure 10

12/17



*Figure 11*



*Figure 12*

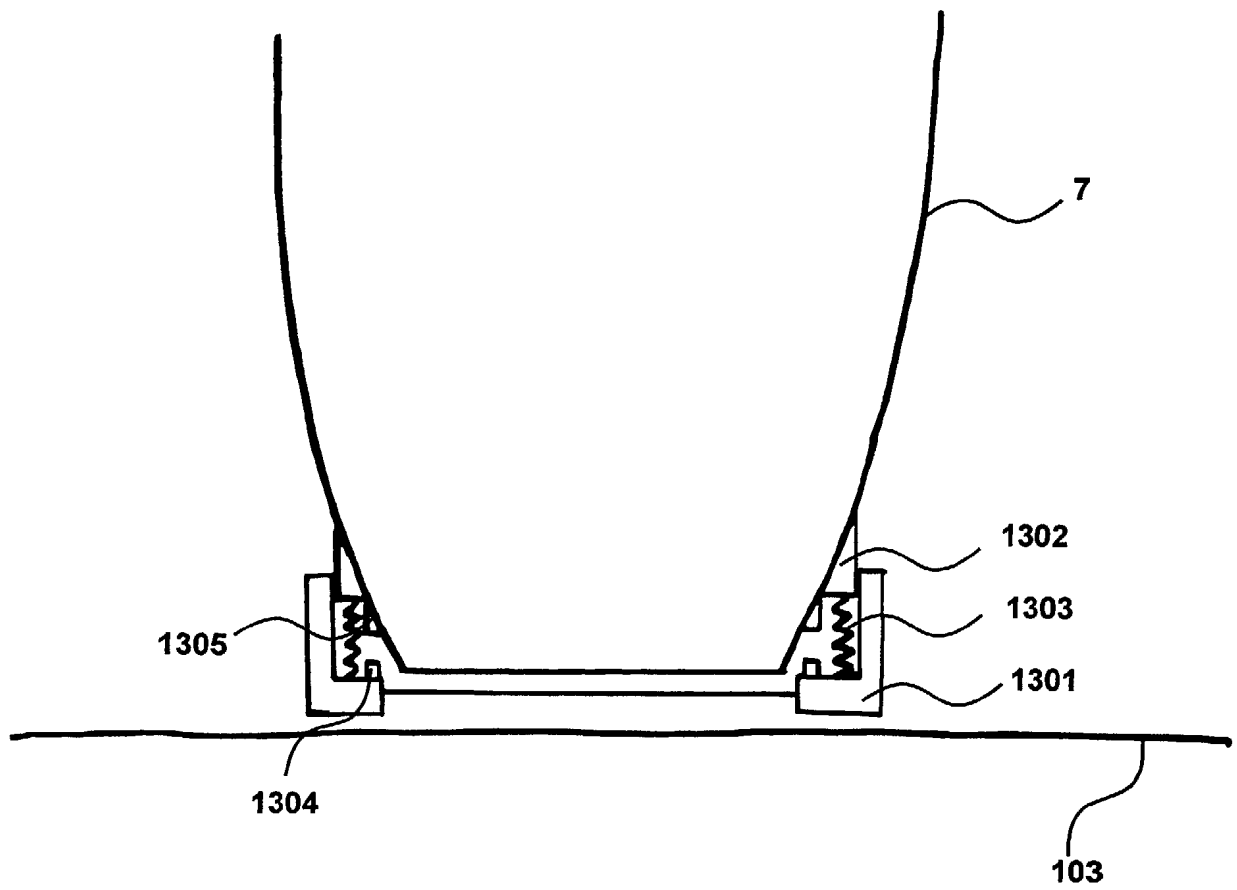
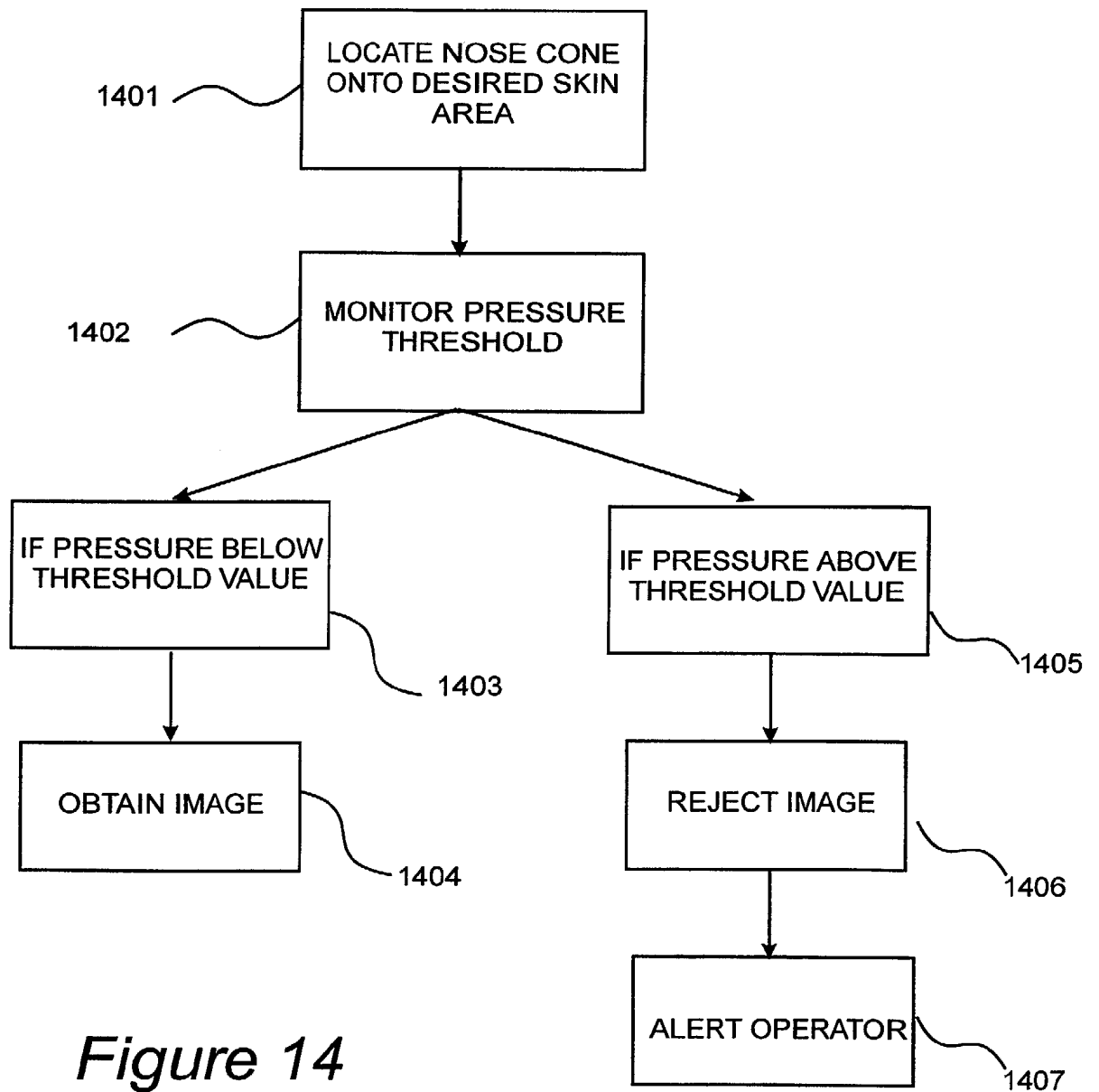
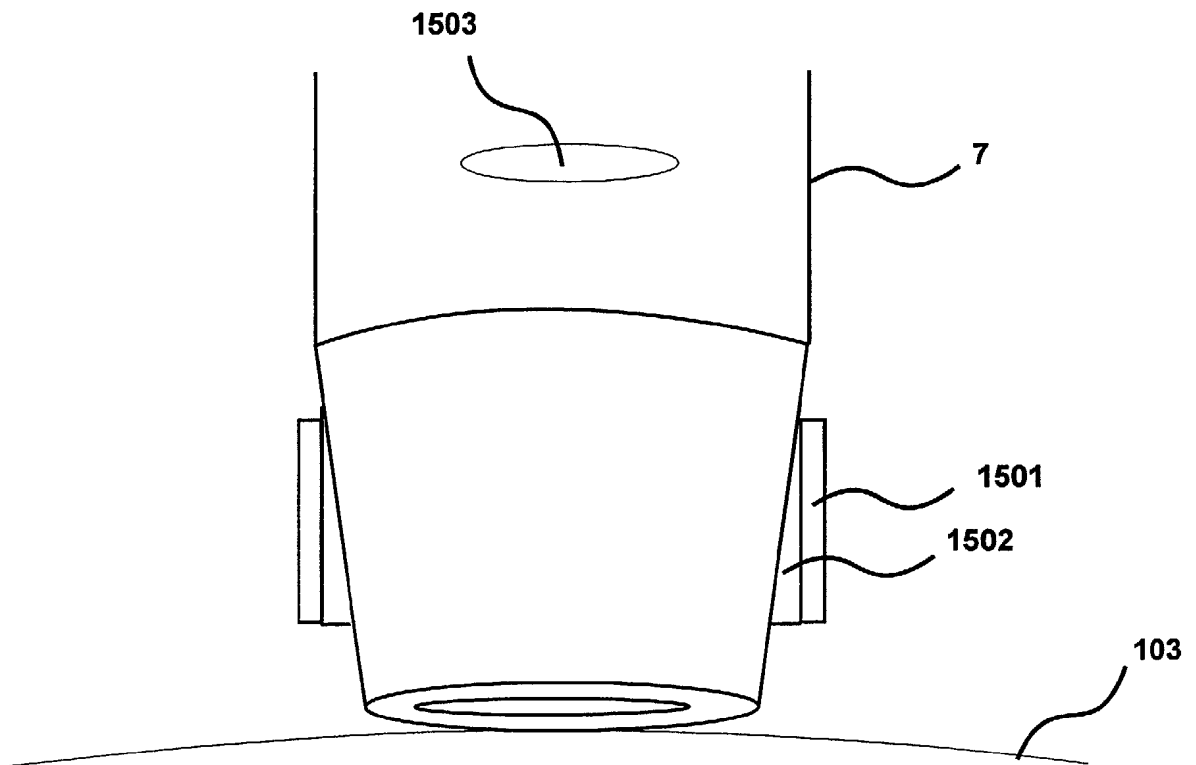


Figure 13

*Figure 14*

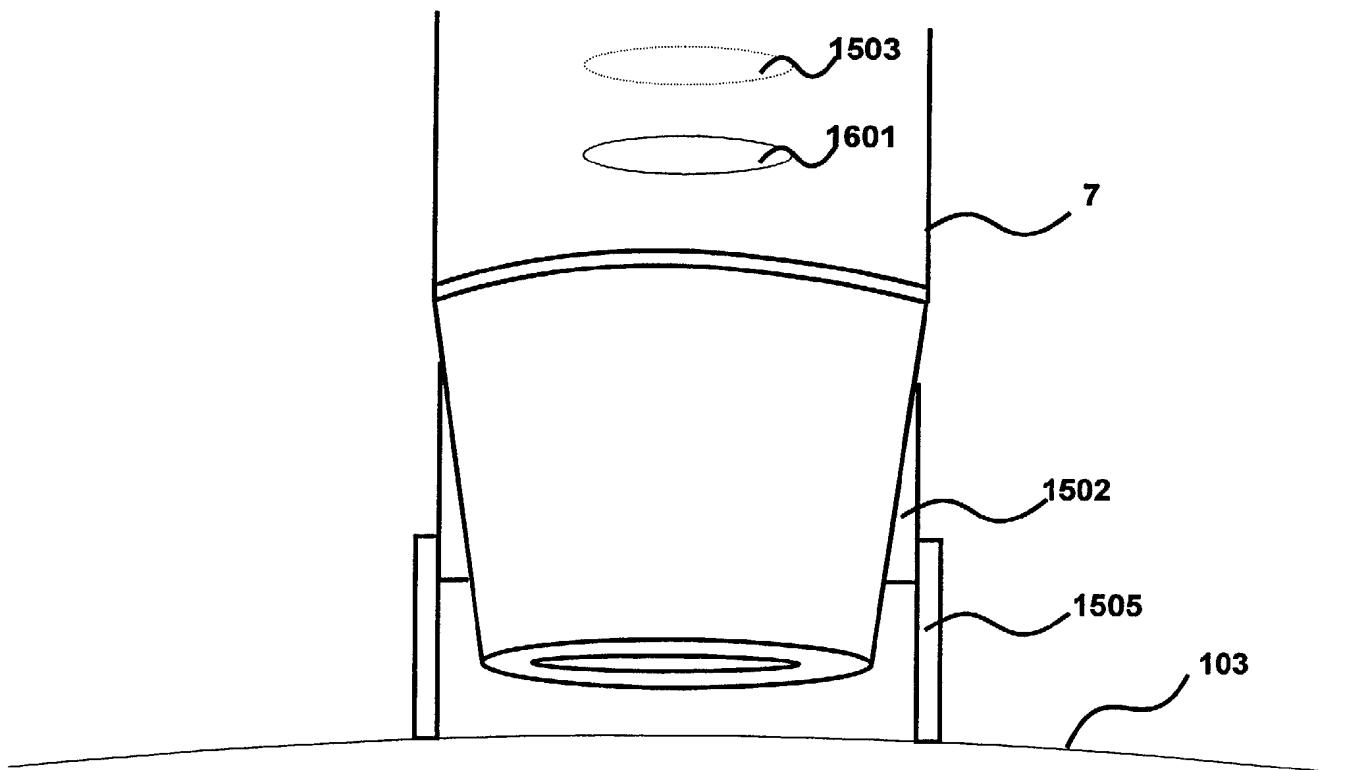


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*Figure 15*

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*Figure 16*

## Skin Diagnostic Aid

### Field of the invention

5 The present invention relates to a skin diagnostic aid and more particularly to a nose cone for use with skin illumination and remitted light detection apparatus as described in UK Patent Application Number 00 10 888.6.

### Background to the invention

10 Conventional methods for the diagnosis of skin ailments involve the examination of the surface characteristics of a skin lesion. In addition, and dependant on the skin condition, a proportion or entire area of a skin lesion may be surgical excised and used for histological examination under a microscope.

15 There are a variety of skin conditions where the provision of histological information rapidly would be a valuable adjunct to enable the efficient diagnosis of a skin ailment. In the example of a malignant melanoma, histological information could be vital to determining the prognosis of the disease. For instance, the ingression of melanocytes into the papillary dermis and in particular the depth of ingression has been correlated to the prognosis  
20 of the disease (Neville, C.D. "Melanoma: Issues of Importance to the clinician", British Journal of Hospital Medicine, 1995). For this reason, a device which could provide histological information about an area of skin rapidly and by a non-invasive technique would be a distinct advantage.

25 The principal chromophores located in the skin include melanin, haemoglobin, oxy-haemoglobin and collagen. In normal healthy skin, melanin is located exclusively in the epidermis, and haemoglobin and oxy-

haemoglobin are located primarily in the papillary dermis and to a lesser extent the reticular dermis. Collagen is located throughout the dermis, with the highest concentration residing in the reticular dermis. Abnormalities in the distribution of such chromophores can provide valuable information about the histology of a skin ailment and can be obtained by detecting and interpreting the distribution of different chromophores within the skin.

Our co-pending United Kingdom patent application numbers 99 12 908 and 99 25 414 relate to advances and improvements in the determination of the concentration and distribution of chromophores within the skin. In particular, United Kingdom patent application number 99 12 908 relates to methods and apparatus by which the histology of the skin may be determined and the identification of the presence depth and concentration of chromophores within the skin. United Kingdom patent application number 99 25 414 relates to a method and apparatus for providing the information of the skin structure, more particularly, to mapping the surface of dermal papillae.

Furthermore, our co-pending United Kingdom Patent Application Number 00 10 888.6 relates to an apparatus and methodology for determining the distribution of chromophores within the histological layers of the skin. An example of the skin illumination and remitted light detection apparatus to which the present invention relates is illustrated in *Figure A*. The skin illumination and remitted light detection apparatus has a housing 1 onto which is mounted a display screen 2 with a touch screen operation. A handset 3 is stored on the housing 1 when not in use. The handset 3 is connected to the internal system of the equipment by a flexible metal tubing 4 which contains a bundle of optical fibres, which transmit light from a source contained within the housing 1, and carries signals from a detector to a computer located within the housing 1. The apparatus is supported by

castors 5, which enable the equipment of the invention to be conveniently moved into a required location.

In use an operator 6 removes the handset 3 from its stored position in the housing 1 and holds the free end 7 of the handset 3 against the target area 8 of the skin of a patient 9, as shown in *Figure B*. The operator 6 may then select options from the touch-screen 2 to initiate the illumination and imaging of the skin area.

The images obtained are displayed in a variety of formats on the display screen and the operator 6 can select specific representations and view the presence of specific chromophore constituents of the skin by selecting options from the display screen 2. The images are interpreted by a suitably trained operator and differences in the distribution of chromophores between the image obtained and the predetermined models of normal healthy skin can be visualised.

Following the imaging of the skin, the light tube 3 is replaced within the housing and a printout of the images obtained for recording purposes.

It has been found that there are four distinct problems associated with the handset 3 and more particularly with the nose cone, which are detailed below.

#### Problem 1

It is clearly visible in *Figure B* that the nose cone is contacted directly onto the skin surface. It is during this procedure that the nose cone may be come contaminated with material associated with skin surface. The current approach to remove such material is to wipe the glass surface with an alcoholic wipe. However, such a procedure may not result in complete removal contaminants from the skin surface or the glass aperture.

#### Problem 2

In addition, when the nose cone is located adjacent to areas of skin, such as a finger or nose, where the skin surface is not a smooth flat surface, ambient light or stray light from the surroundings may access the detector and give rise to errors in the measurement of remitted light.

5           Problem 3

A further disadvantage of the current nose cone is the absence of a mechanism for controlling the pressure by which the nose cone is applied to the skin surface. This is particularly significant in, for example, situations where the apparatus is used for mapping the topology of the dermal papillae and applying too much pressure to the skin results in a flattening of these papillae.

10           Problem 4

A final disadvantage of the current nose cone is the requirement to provide a clinician with a clinical view. By clinical view we mean a view of the macroscopic skin surface which is a valuable adjunct to the images of light remitted from an area of skin for which the apparatus to which the present invention pertains is designed.

The present invention is concerned with overcoming the above mentioned problems or at least significantly reducing them.

20           According to the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises barrier means

25

configured to prevent direct contact between said glass aperture and said skin.

According to a second aspect of the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises an ambient light exclusion means to prevent ambient light accessing said glass aperture.

According to a third aspect of the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises a pressure detection means configured detect a threshold level of pressure between said light tube and the skin.

According to a fourth aspect of the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to

select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises a means for locating said glass aperture a defined distance from said skin surface such that a clinical view of the skin surface is obtained.

### **Brief Description of the Several Views of the Drawings**

How the invention may be carried out will now be described, by way of example only, with reference to the accompanying drawings, in which:

*Figure A* is a perspective view of an example of the equipment to which the present invention relates;

*Figure B* is a schematic representation of the apparatus of *Figure 1* in use;

*Figure 1* is a perspective representation of the nose cone of the apparatus shown in *Figures A* and *B*;

*Figure 2a and 2b* are perspective representations of an example of disposable nose cones;

*Figures 3* is a schematic representation of a nose cone fitted with a disposable film cover;

*Figure 4* is a schematic representation of a transparent film coating that may be applied to the skin;

*Figure 5* is a cross-sectional view of the film shown in *Figure 6*, taken along the line X-X';

*Figure 6* is a schematic representation of a nose cone in contact with a finger;

*Figure 7* is a flow chart illustrating an example of an operational sequence to detect the presence of stray light;



*Figure 8* is a schematic representation of a film cover attachment;

*Figure 9* is a schematic representation of an alternative film attachment shown in *Figure 8*;

5        *Figure 10* is a schematic representation of a nose cone in contact with a skin surface;

*Figure 11* is a schematic representation of a nose cone configured to detect the pressure applied to the skin;

*Figure 12* is a schematic representation of an alternative embodiment of the nose cone shown in *Figure 11*;

10        *Figure 13* is a schematic representation of a further nose cone equipped with a mechanical means for determining the pressure with which the nose cone is applied to the skin;

*Figure 14* is a flow chart showing an example of an operational sequence configured to prevent over pressurising the skin below;

15        *Figure 15* is a perspective view of a nose cone with spacer legs in an upright position; and

*Figure 16* is a perspective view of a nose cone shown in *Figure 15* with the legs in a down position.

20        In the drawings the same reference numerals are used for like or corresponding parts in each of the Figures.

### **Best Mode for Carrying Out the Invention**

25        Figure 1 shows a schematic representation of a light pipe 3 having a nose cone 7 with a transparent glass aperture 102 defined by the nose cone ending 101. Illumination from the source, is transmitted from a source located within the housing 1 to the light pipe 3 (see *Figures A and B*) and illuminates the skin 103 through the transparent glass aperture 102. Also shown within

figure 1 is a lesion **104**, for example a mole, in which the distribution of chromophores is to be examined.

To obtain an image, the skin **103** is contacted directly against the aperture **102**. Loose skin and material on the skin surface such as, for example, skin oils, creams etc, leaves a residue on the glass aperture **102** and which, if not removed, will affect the quality of subsequent images.

A nose cone according to the present invention is illustrated in *Figures 2a and 2b*. *Figure 2a* illustrates a schematic representation of a disposable nose cone **7** with a nose cone ending **101** incorporating a glass aperture **102**.

The nose cone **7** illustrated in *Figure 2a* comprises a male connection member **201** which is receivable within the handset body to form a resistive fit to secure the nose cone in position. *Figure 2b* illustrates another disposable nose cone similar to that shown in *Figure 2a* with the exception that the nose cone body **7** is elongated with a nose cone ending **101** and a glass aperture **102** of smaller dimensions to the corresponding nose cone illustrated in *Figure 2a*.

To accommodate the differing dimensioned nose cone, a means is provided to adapt the detective field of the detector to accommodate the appropriate sized glass aperture. This is achieved in the present embodiment by the provision of an electrical contact on the nose cone such that, upon attaching the nose cone **7** to the handset **3**, a contact is made with a second electrical contact provided on the handset **3**. The contact will be configured such that each different dimensioned nose cone interacts with a specific electrical contact on the hand set. Upon electrical contact between a contact on the nose cone and a contact on the handset, the lens which focuses the light remitted from the skin onto the detector is automatically moved to a predetermined position which adapts the detective field of the detector to

correspond with that of the aperture of the nose cone fitted. Consequently, a variety of nose cones of differing dimensions are provided enabling the selection of different image areas.

Alternatively, the lens may be repositioned by a mechanical means, wherein the nose cone carries a probe which, upon location of the nose cone on the handset, is received by the receptacle which moves a slidably mounted lens to the required position corresponding to the length of the probe. Each different dimensioned nose cone will possess a different length probe which determines the final lens position and hence ensure correct focus of the image field of the detector within the handset onto which it is mounted.

The desired nose cone is provided within a sealed bag from which it is removed and mounted onto the handset. Upon use, the nose cone is contacted directly with the skin surface and the skin imaged as described in our previous applications. Following use, the nose cone 7 is detached from the handset and discarded. For subsequent images, a second clean nose cone is attached to the handset.

An alternative embodiment of the present invention is illustrated in *Figure 3*. Attached to a nose cone 7 is a transparent film 302, which forms a covering over the nose cone ending 101 and the transparent glass aperture 102. The film serves as a physical barrier between the glass aperture 102 and the skin and thus prevents contaminants on the skin adhering to the glass. The film 302 is mounted taught within a plastic clip 303 which comprises an arm 304 which extends adjacent to the external surface of the nose cone body 7. In the preferred embodiment, the nose cone 7 is provided with an annular lip 301 which extends about the circumference of the nose cone. The arm of the plastic clip 304 comprises a recess 305 configured to

receive the annular lip **301** of the nose cone **7**, such that the plastic clip **303** and the transparent film **302** mounted therein is held flush with the nose cone end **101** and the glass aperture **102**.

5 The film **302** is preferably prepared from material which is uniformly transparent to light of visible and infra-red wavelengths. Examples of suitable materials would include polyethylene, polyesters, polypropylene, polystyrene, PBDF and polyvinylchloride. The plastic film may also be coated with an adhesive to improve the adherence of the film to the skin.

10 An example of an alternative film that may be incorporated into the clip illustrated in *Figure 3* is shown schematically in *Figure 4*. Located on a first side of the transparent film **302** is a second layer of an optical reflective index matching oil **401** within a defined area **402** which corresponds to the area of the glass aperture **102** of the nose cone **7**. In the preferred embodiment the optical matching index oil is Heine Mineral Oil although any suitable optical  
15 index matching oil would suffice such as olive oil or ultrasound coupling gel. In use the optical matching oil reduce reflections from the skin surface. The oil coats the skin on contact diffusing into cracks and abrasions on the skin surface and reducing optical inhomogeneities due to the skin topology.

Also illustrated in *Figure 4* is a further layer of adhesive **403** of defined  
20 area **404** which encircles the optical index matching oil area **402**. This arrangement provides for securing the film **302** to the skin surface of a subject providing an area of optical index matching oil **402** of comparable size to the glass aperture **102** such that, upon illumination, light incident from the skin encounters a layer of optical index matching oil prior to contacting  
25 the surface of the skin.

*Figure 5* shows a cross-section through the film illustrated in *Figure 4* along the lines X-X'. The film **302** has, mounted on a first side, a second layer

of optical index matching oil **401** surrounded by a further layer of adhesive **403**. As previously described, the film is contacted with the skin via the first side, upon which the second layers of optical index matching oil and adhesive are mounted, and the second side is contacted with the glass aperture preventing contaminants accessing the glass aperture of the nose cone.

Alternatively, the transparent film could be applied directly to the skin of the patient and the nose cone of the handset located against the exposed side of the film to image the area of skin. The film may be secured to the skin by a layer of adhesive. In addition, a layer of optical index matching oil could be provided as previously described with reference to *Figures 4 and 5*.

The films incorporated in the present invention could also comprise a bar code which can be read by a bar code reader mounted within the handset or by the system intended for measuring the light remitted from the skin itself. Consequently the image can be correlated with a specific patient by the bar code for recording purposes. Such a system, could also be used to prevent re-use of a film and hence, cross contamination with material collected from the skin during a previous image process. Example of alternative datamarkings which can be used instead of bar codes include snowflake markings, alphanumeric codes or various forms of optical characters.

Furthermore, the film can be marked with a medical pen to identify areas of a lesion which may be excised. For example, in the case of a malignant melanoma, the images obtained by the apparatus of *Figures A and B* will indicate the distribution of melanin beneath the surface layers of the skin. Consequently, it may be apparent that a larger area of the lesion requires removal compared to what is evident by a surface examination. A

clinician will be able to mark or transfer a mark of the area to be excised onto the film which is subsequently used as a guide to a surgeon when removing the lesion.

The following section will describe examples of embodiments of the invention designed to address the problem of stray light accessing the detector.

A schematic representation of an example of apparatus according to the invention in use imaging a skin surface of substantial curvature is illustrated in *Figure 6*. The light pipe 3 comprises a nose cone 7 which further houses a nose cone end 101 with a glass aperture 102 mounted therein. Located adjacent to the glass aperture is a finger, represented by the object 601. The finger 601, by virtue of the size and curvature, does not form a complete contact with the glass aperture and consequently stray light (or ambient light from the surroundings) accesses the detector increasing the background intensity and obscuring the image of light remitted from the skin. This makes the interpretation of the image less accurate and, in situations where the light remitted from the illuminated area of skin is low, the remitted light may be undetectable relative to the intensity of stray light accessing the detector.

To prevent images being obtained in a situation where too much stray light is present a safety operational sequence is incorporated into the operation of the apparatus to which the invention relates. The operational sequence is illustrated in *Figure 7*.

The light pipe is removed from the apparatus and located on the desired area of skin 701. An image is recorded in the absence of incident illumination 702. The intensity of the image detected will depend on two factors, namely the dark current of the detector (which is known during

normal operation) and the presence or absence of stray light accessing the aperture. Consequently, the intensity of the image at one or more points on the detector is set to a predetermined threshold level of stray light considered acceptable. If the image intensity at one or more points is below the defined  
5 threshold **703** the normal imaging process continues **704**. If the image intensity at one or more points is above a predetermined threshold level of illumination **705** the image will be rejected **706** and the operator alerted by an alarm or visual message **707** to signify that there is insufficient contact between the desired skin area and the glass aperture.

10 An example of an embodiment of the invention configured to prevent stray light accessing the detector is shown in *Figure 8*. The nose cone **7**, with glass aperture **101** defined by nose cone end **102**, is contacted with a finger, represented by oval object **601**. Located in between the nose cone ending and the finger **601** is a transparent film **302**, which prevents contaminants  
15 from surface of the finger contacting the glass aperture. The transparent film **302** is fixed to the nose cone by an adhesive coating **802**. A circular deformable foam ring **801** is attached to the film such that stray light from the surrounding is blocked from accessing the glass aperture **102**. Any suitable deformable and optically opaque material would suffice in place of the foam  
20 ring **801**, suitable examples of which include pigmented silicone rubber and visco-elastic polymers such as a material known as "silly putty" or Plasticine<sup>RTM</sup>.

An alternative embodiment of the invention is shown in *Figure 9*. A nose cone **7** is provided with an annular lip **301**. A finger **601** is orientated  
25 adjacent to the glass aperture **102** with a transparent film located in between. The transparent film **302** is mounted within a plastic clip **303** which receives the nose cone end **101** and is clipped into place by a groove **301** which

receives the lip **301**, as previously discussed with reference to *Figure 3*.

An opaque curtain **901** extends from the clip to associate with the finger **601** to prevent stray light from the surroundings accessing the glass aperture **102**. The curtain can be made from any visually opaque material, with fabric and polymer films the most preferred materials.

During skin imaging it is preferable to have the skin flat and pressed against the glass aperture of the handset such that an even illumination is provided across the skin surface. Consequently, a degree of force is required when pressing the handset onto the skin surface. An operator familiar with the device will have experience of the amount of pressure required, but an unfamiliar operator may provide too much or too little force. Applying too much force is detrimental in situations where the apparatus to which the invention pertains is used for mapping the topology of the dermal-epidermal junction.

*Figure 10* illustrates a schematic representation of a nose cone **7** of the skin illumination apparatus in contact with a skin surface **103**. The skin is shown in cross section illustrating the stratum corneum **1001** dermo-epidermal junction **1002** and the boundary between the dermis and the sub-cutaneous tissue **1003**. In normal skin the dermo-epidermal junction exists as an undulating layer of peaks and troughs which define finger like projections or "papillae". In *Figure 10* this layer is shown schematically as peaks **1004** and troughs **1005**. If the nose cone **7** is pressed against the skin surface **103** with more force than is required the skin surface is compressed between the nose cone **7** and the pressure exerted by the underlying sub-cutaneous tissue **1003**. Hence, the thickness of the skin is reduced and the dermal papillae are squashed as illustrated at **1006**. This may lead to false interpretation of the data, particularly in conditions where a flattening of the



dermal papillae is diagnostic feature of a skin condition such as, for example, basal cell carcinoma.

*Figure 11* illustrates a modified nose cone receivable on the handset of the apparatus to which the invention pertains. The nose cone 7 comprises the usual nose cone end 101 which defines a transparent glass aperture 102 through which the skin is illuminated. In addition, mounted within the nose cone end 101 are two load cells 1101 and 1102 which are contacted with the skin. The load cells produces an electrical output corresponding to the pressure. The load cell is calibrated to detect an acceptable range of pressure between the skin surface and the nose cone 7. If the pressure exceeds a predetermined threshold level, the apparatus is configured to prevent an image been obtained and thus prevent a false representation of the skin surface being imaged.

*Figure 12* shows an alternative embodiment of the present invention whereby the nose cone 7 is provided with a load cells 1101 and 1102 situated between the nose cone and handset 3. Applying pressure to the nose cone 7 in turn transfers pressure to the junction between the nose cone 7 and the handset 3. Similarly, to the embodiment illustrated in *Figure 11*, the load cells are configured to detect pressures above a predetermined maximum.

A mechanical means by which a maximum threshold pressure is detected is shown in *Figure 13*. The nose cone 7 is provided with a circular skin-contacting member 1301 attached to a support 1302 on the nose cone by a resilient spring 1303. A transparent film 302 is mounted within the aperture defined by the skin-contacting member 1301. The nose cone is orientated over an area of skin to be imaged and pressed against the surface 103. The skin contact member is forced towards the nose cone body 7,

compressing the resilient spring **1303**. If the pressure exceeds a defined threshold, the skin contact member is forced such that the protuberances **1304** contact the microswitch **1305** mounted on the nose cone **7**. The actuation of the microswitch triggers an alarm or visual message alerting the operator to the over pressuring of the skin area and prevents an image being obtained until the pressure is reduced below the predetermined threshold value.

*Figure 14* is a flow chart illustrating an example of an operational sequence employed to prevent over pressurising an area of skin. The nose cone is located over the desired area of skin to be imaged **1401**. The load threshold is monitored by the pressure detection means **1402**. If the pressure is too high **1405**, indicated by a signal from the pressure detection means, then the image is rejected **1404** and the operator alerted by audio alarm of visual signal **1407**. If the pressure is below the defined threshold **1404**, the image is obtained as per the normal operational procedure of the skin measurement apparatus **1407**. Consequently, when the operator is alerted to the over pressuring of the skin, the pressure applied may be reduced to below the threshold upon which an image is obtained as per the standard imaging procedure.

A further modification to the nose cone is illustrated in *Figure 15*. During use of the apparatus to which the invention relates, it is advantageous to provide a "clinical view" which, in other words, is an image of the skin surface. In *Figure 15*, the nose cone **7** of the handset is equipped with a two leg members **1501a** and **1505b** rotatably mounted onto a support **1502**. In *Figure 15*, the legs are in the "up position" and the handset is configured for illuminating the skin surface and detecting the light remitted. A lens **1503**, mounted within a handset **3**, focuses the remitted light onto a detector (not

shown). To obtain a clinical view the legs are rotated into a down position, as illustrated in *Figure 16*. The nose cone end **101** is lifted from the skin surface **103** and the position of the lens adjusted to focus on the skin surface **103**. In a preferred embodiment the detector is provided with an auto-focus system which automatically moves the lens **1503** mounted within the handset to focus on the skin surface **103**. Alternatively, the lens may be moved to predetermined position by a mechanical means associated with the rotatable leg members. For example, when the leg members are in a "up position" the lens resides in a fixed position **1503** during imaging of chromophores within the skin and upon moving the leg members to a "down position" the lens is moved to a second predetermined position **1601** to focus on the skin surface.

Although the nose cone is spaced above the skin surface by the leg members in the embodiment illustrated in *Figures 15* and *16*, any spacing means would suffice, such as, for example, a spacer ring or foam ring of defined dimensions such that the nose cone is spaced an optimal distance from the skin surface.

## Claims

1. A skin illumination and remitted light detection apparatus,  
comprising

5 a light tube defining a transparent glass aperture contactable with the  
skin,

illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident  
10 on said detection means,

illumination intensity selection means to select the intensity of light  
incident on the detection means, characterised in that

said apparatus further comprises barrier means configured to prevent  
direct contact between said glass aperture and said skin.

15

2. A skin illumination and remitted light detection apparatus,  
comprising

a light tube defining a transparent glass aperture contactable with the  
skin,

20 illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident  
on said detection means,

illumination intensity selection means to select the intensity of light  
25 incident on the detection means, characterised in that

said apparatus further comprises an ambient light exclusion means to  
prevent ambient light accessing said glass aperture.

3. A skin illumination and remitted light detection apparatus,  
comprising

a light tube defining a transparent glass aperture contactable with the  
5 skin,

illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident  
on said detection means,

10 illumination intensity selection means to select the intensity of light  
incident on the detection means, characterised in that

said apparatus further comprises a pressure detection means  
configured detect a threshold level of pressure between said light tube and  
the skin.

15 4. A skin illumination and remitted light detection apparatus,  
comprising

a light tube defining a transparent glass aperture contactable with the  
skin,

20 illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident  
on said detection means,

illumination intensity selection means to select the intensity of light  
25 incident on the detection means, characterised in that

said apparatus further comprises a means for locating said glass  
aperture a defined distance from said skin surface such that a clinical view of

the skin surface is obtained.



INVESTOR IN PEOPLE

**Application No:** GB 0016392.3  
**Claims searched:** 1

21

**Examiner:** David Brunt  
**Date of search:** 25 January 2001

## **Patents Act 1977**

### **Search Report under Section 17**

#### **Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): G1A (AAMX, AFE)

Int Cl (Ed.7): A61B (5/00, 5/103), G01N (21/47)

Other: Online: EPODOC, JAPIO, WPI

#### **Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
Y	GB 2156127 A (RICE) see Fig.2	1
Y	EP 0826335 A1 (ESC) see column 5 lines 13-31	1
Y	WO 99/05961 A1 (SPECTRX) note various references to calibration and wavelength selection	1
Y	WO 98/22023 A1 (UNIV BIRMINGHAM) see p.17 ll.15-19 and p.18 ll.18-23	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

# (12) UK Patent Application (19) GB (11) 2 368 020 (13) A

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**A61N 5/06 5/067**

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**A5R REHR**

(56) Documents Cited  
**GB 2356570 A** **GB 2336545 A**  
**GB 2272158 A** **EP 0884066 A2**  
**EP 0159446 A2** **WO 98/38933 A1**  
**WO 96/33773 A2** **WO 00/74782 A1**  
**WO 00/32272 A1** **US 5549660 A**

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Online: **EPODOC, JAPIO, WPI**

(54) Abstract Title  
**Treatment of acne vulgaris skin condition by irradiation with light of specific wavelengths to target specific chromophores & stimulate collagen production**

(57) There is provided apparatus for the cosmetic treatment of a skin condition which comprises means for delivering illuminating radiation to a target skin zone or structure.

The skin condition may be acne vulgaris or Rosacea.

A method for the treatment of such a skin condition comprises directing illuminating radiation (including that of a predetermined wavelength) to a target skin zone in accordance with a predetermined delivery regime in order to effect (preferably contemporaneously) at that zone:

- (a) a reaction which leads to at least partial disabling or eradication of the cause of the skin condition and
- (b) non-ablative heating of the tissue in order to stimulate an inflammatory response to a degree sufficient to effect collagen production.

The illuminating radiation may be delivered continuously or in pulse mode (eg with pulses in the range 10  $\mu$ s to 100 ms, especially 50  $\mu$ s to 10 ms) and its source may comprise laser diodes or light emitting diodes (LED's), with filters for the required selected wavelength, if necessary.

The wavelength of the illuminating radiation is preferably in the range 400-1500 nm, especially 500-650 nm and preferably comprises a narrow wavelength band in the range 570-595 nm (yellow). The energy density is preferably in the range 0.5-5 J/cm<sup>2</sup>, with the apparatus advantageously being configured to allow variable selection of energy densities within that range but inhibit output above that range.

For acne vulgaris, interaction (a) above is achieved by targeting the chromophore porphyrin in haemoglobin which aggregates at the site of inflammation. Excitation with yellow light (ca 585 nm) produces singlet oxygen photochemically which destroys the adjacent bacterium responsible for acne vulgaris (propionibacterium).

Interaction (b) above is achieved by targeting the chromophore (oxy)haemoglobin in the dermal vasculature. The resulting photothermolysis effect stimulates, via inflammatory mediators, the production of fibroblasts which are responsible for the production of collagen, the skin's natural filling material, which improves skin texture and appearance.



Cosmetic Treatment Of Skin Conditions

The present invention relates to cosmetic treatment of skin conditions such as, for example, Acne Vulgaris.

5

Acne Vulgaris is a condition of the sebaceous glands which affects 80% of individuals between the ages of 11 and 30. It is not confined to these age groups however and can affect all ages from neonates to the elderly. Factors which are considered of primary significance to the condition include an increase in the production of sebum, abnormal follicular keratinisation, the presence of Proprionibacterium and subsequent inflammation.

15 Dependant on the size, content, and depth of the inflamed acne lesion, it is defined as a papule (less than 0.5cms in diameter), nodule (elevated solid lesion > than 0.5cms) pustule (a papule what contains purulent material) or a cyst (nodule that contains fluid or semisolid matter).

20

Hair follicles are minute passages in the skin, which allow hairs to grow and produce sebum secretions from sebaceous glands which are housed within the hair follicle. Due to increased androgen levels or an excessive reaction by the sebaceous glands to androgen production, the sebaceous glands enlarge resulting in increased secretion of sebum which along with the keratinisation process of the epithelial cells, clog the hair follicle. Initially these blockages are microscopic then develop into whiteheads or blackheads (Comedones). Congested follicles are an ideal medium for growth of bacteria. When sebum levels are

30

increased, the skin commensal propionibacterium ingest the clogged sebum under the skin and chemicals are produced which trigger the immune system to initiate the inflammatory changes and erythematous macules associated with Acne Vulgaris.

Inflammation is the body's response to invasion of pathogens and the redness associated with the acne lesions is the result of increased blood flow whereby the white blood cells invade bacterial cells and damage tissue and produce pus. Other fluids flood to the area and collect at the site of the inflamed tissue.

The approaches which are currently used for tackling Acne Vulgaris include Drug therapies (Systemic antibiotics, cortisone injections, Dianette (women only contraceptive pill, Roaccutane, Retinoids), PUVA (Psoralen and Ultra Violet light, type A), UVB Phototherapy, Dermalux (a system using a combination of red and blue light to treat acne), Peeling agents, laser resurfacing, Dermabrasion and Microdermabrasion.

According to the present invention, there is provided a method for the cosmetic treatment of a skin condition (particularly acne vulgaris), the method comprising directing illuminating radiation, including illuminating radiation of a predetermined wavelength, toward a target zone of skin in accordance with predetermined delivery regime in order to effect at the target zone a plurality of interactions, including:

- a) a reaction leading to at least partial disabling or eradication of the cause of the skin condition; and,
- 5        b) non-ablative heating of tissue stimulating an inflammatory response to a degree sufficient to effect collagen production.

The two-fold interaction system effected by the  
10 illuminating radiation provides an extremely effective cosmetic effect in that the interaction acts to clear up the skin condition and also stimulates the production of collagen to improve skin appearance (minimizing the appearance of scarring caused by the condition). A feature  
15 of the technique of the invention is that efficacy is achieved without the need of any other topically applied agent or any invasive or ablative procedure.

It is preferred that the interactions a) and b) defined  
20 above occur substantially contemporaneously.

The radiation is typically low intensity (avoiding ablation at or below the skin surface) and typically primarily of wavelength at or about the wavelength of yellow light  
25 (585nm) for reasons explained in detail later. Absorption of light is through the dermal vasculature having no adverse effects on the epidermis.

Desirably, the reaction leading to at least partial removal  
30 or disabling of the cause of the skin condition is a photochemical reaction.

Beneficially, the heating interaction is a photothermal effect caused by selective absorption of the predetermined wavelength light, typically by a preselected chromophore.

5 For Acne Vulgaris the chromophore targeted to combat the  
propionibacterium is porphyrin in the connective tissue.  
This tissue bound photosensitizer when excited from light  
of a certain wavelength (approximately the wavelength of  
yellow light - 585nm), produces a photochemical reaction  
10 resulting in the production of singlet oxygen thereby  
destroying the bacterium.

Propionibacterium is averse to oxygen (anaerobic) and  
relies upon chemicals known as porphyrins in skin tissue.  
15 Porphyrin is usually innocuous in the absence of light. It  
is however photosensitive and when exposed to light of the  
required wavelength the photochemical reaction occurs.  
This results in a transition from the porphyrin's ground  
state to a reactive triplet state. At this level, a  
20 reaction with molecular oxygen creates singlet oxygen.  
Through the medium of a suitable light source, to activate  
the porphyrins to produce singlet oxygen, the bacterium  
responsible for Acne Vulgaris can be cleared in a cosmetic,  
pain-free, non-invasive and efficient manner.

25 Vasodilation and hyperemia are integral parts of the  
inflammatory response, including response to infection.  
Therefore any inflammatory/infective focus contains a  
disproportionate concentration of red blood cells.

30 Porphyrin molecules are contained in the hem of

haemoglobin so that any inflammatory or infective focus contains a concentration of natural porphyrin. Activation of this porphyrin using, for example, yellow (585nm) light releases substances which destroys adjacent toxins such as bacteria in acne.

Similarly, any acute inflammatory condition of skin such as rosacea will be helped although the exact toxin may be unknown.

10

Secondly, targeting the chromophore haemoglobin in the dermal vasculature plexus to create thermal injury stimulates the production of fibroblasts which is responsible for collagen production. The stimulated collagen produced is the skin's natural filling material, which will cosmetically improve skin texture and appearance. Exposure to light (of a relevant selected wavelength) results in a selective, non-ablative photothermolysis effect in the target chromophore, that is oxyhaemoglobin. The interaction of the radiation (light) within the dermal vascular plexus induces an inflammatory/growth response. This results in the release of inflammatory mediators from the endothelial cells through the vessel walls and into the dermal interstitium where they stimulate fibroblast activity. Fibroblasts are quiescent unless stimulated by inflammatory mediators. This creates a response by the fibroblasts to initiate tissue repair mechanisms which will in turn produce enhanced new collagen which is the skin's natural filling material and will improve skin texture and appearance.

30

The energy density of the energy delivered should be accurately controlled and monitored so as not to exceed a predetermined threshold level.

5 In order to stimulate fibroblast activity, the incident light must be absorbed in the microvasculature to release the necessary mediators which trigger fibroblast activity and hence collagen production.

10 Certain wavelengths of above, for example, 600nm (for example, 660nm - red) are not optimum for collagen stimulation as red light is not preferentially absorbed in-  
haemoglobin/oxyhaemoglobin. An alternative option is to use two wavelengths, one with a high absorption in  
15 porphoryin, which has absorption peaks other than those in the yellow region, and at least one wavelength at yellow (570-590nm).

Where the skin condition is Acne Vulgaris it is therefore  
20 preferred that the wavelength of the illuminating radiation comprises a primary wavelength or narrow wavelength band substantially in the range 570-590nm.

Beneficially the radiation delivered is pulsed, the pulse  
25 duration preferably being less than the thermal relaxation time of the target structure. This limits and controls the thermal damage done to the target structure, and controls the correct thermal and chemical response as required.

30 The photochemical interaction is typically dependent upon the number of incident photons, so the photons may be

delivered in pulsed or continuous wave mode. However, for the stimulation of collagen, pulsed operation is preferred to ensure delivery of the required energy regime to cause the triggering of the release of inflammatory mediators.

5

The light (radiation) source may comprise laser sources (such as laser diodes) or light emitting diodes (LED's) if necessary with appropriate filter(s) to promote propagation of the required selected wavelength (or narrow wavelength band).

10

Also by using pulsed operation, light emitting devices (particularly LED's) may be driven harder to produce more light output. A typical LED can operate at a drive current of 50mA in continuous mode, whilst in pulsed operation, for short periods, the same diode can be pulsed at current of around 200mA. This pulsed operation may be between  $1\mu\text{s}$  to 100msec ( $1\mu\text{s}$  to 5ms preferred). This will allow fewer diodes to be used for a given output power requirement or a larger area to be treated with same amount of diodes.

15

20

The target for the light source has to be a material that absorbs a specific wavelength and disregards other wavelengths (chromophore). In accordance with the invention, for Acne Vulgaris, the chromophores may be porphyrin in skin tissue and oxyhaemoglobin in the dermal vasculature.

25

The preferred wavelength (or wavelengths) for this invention will depend upon the skin condition being treated but typically include a wavelength in the range of 400nm to

30

1500nm with a preferred range of 500-650nm. Energy density is in the range of 0.5-5J/cm<sup>2</sup> via a pulsed or continuous wave. For pulsed operation the range is 10μs to 100ms with a preferred range of 50μs to 10ms.

5

According to a further aspect, the invention provides apparatus for cosmetic treatment of a skin condition (particularly Acne Vulgaris), the apparatus comprising illuminating radiation delivery means for delivering  
10 illuminating radiation to a target skin zone or structure.

The apparatus is preferably arranged to output radiation of a discrete wavelength (or narrow primary wavelength band) substantially in or about the range 400nm-1500nm, depending  
15 upon the skin condition being treated. For treatment of acne vulgaris the preferred range is 500nm-650nm, most preferably 570nm-595nm.

The apparatus preferably delivers radiation at an energy  
20 density at the skin surface substantially in the range 0.5J/cm<sup>2</sup> - 5J/cm<sup>2</sup>. The apparatus is preferably configured to inhibit output of energies substantially above this range. Desirably the apparatus is configured to permit variable selection of energy densities within the range.

25

The illuminating radiation may be pulsed or continuous wave. Pulsed energy may be preferred in order to avoid overheating of the target tissue structure (describe above) and produce the appropriate inflammatory response for  
30 collagen production. Pulse duration is preferably substantially in the range 10 microseconds - 100ms



(preferably substantially in the range 50microseconds - 10ms).

According to a further aspect, there is provided a method  
5 for the manufacture of an agent for the treatment of a skin  
condition (particularly Acne Vulgaris), the agent  
comprising illuminating radiation active to effect at the  
target zone the following interactions:

- 10 a) a reaction leading to at least partial disabling  
of the cause of the skin condition; and,
- b) non-ablative heating of tissue stimulating an  
inflammatory response to a degree sufficient to  
15 effect collagen production.

The invention has been primarily described in relation to  
the cosmetic treatment of Acne Vulgaris. It will however  
be appreciated that the two-fold nature of the action  
20 described for the invention has potential with respect to  
other skin conditions, including for example acute  
inflammatory conditions such as Rosacea, depending upon the  
selection of the appropriate chromophore/toxin.

**CLAIMS:**

1. A non-surgical method for the cosmetic treatment of a skin condition comprising directing illuminating radiation toward a target zone of skin in accordance with predetermined delivery regime in order to effect at the target zone a plurality of interactions, including:
  - (a) a reaction leading to at least partial disabling or eradication of the cause of the skin condition; and
  - (b) non-ablative heating of tissue stimulating an inflammatory response to a degree sufficient to effect collagen production.
2. A method according to claim 1, for the cosmetic treatment of Acne Vulgaris.
3. A method according to claim 1 or 2, wherein the illuminating radiation is of a predetermined wavelength.
4. A method according to any preceding claim, wherein the interactions (a) and (b) occur substantially contemporaneously.
5. A method according to any preceding claim, wherein the reaction leading to at least partial disabling or eradication of the cause of the skin condition is a photochemical reaction.

6. A method according to any preceding claim, wherein the illuminating radiation delivered is pulsed.
7. A method according to claim 6, wherein the pulse duration of the illuminating radiation is less than the thermal relaxation time of the target structure.
8. A method according to claim 6 or 7, wherein the pulse duration of the illuminating radiation is between  $10\mu\text{s}$  to 100ms.
9. A method according to claim 8, wherein the pulse duration of the illuminating radiation is between  $50\mu\text{s}$  to 10ms.
10. A method according to any preceding claim, wherein the wavelength of the illuminating radiation is in the range of 400nm to 1500nm.
11. A method according to any preceding claim, wherein the illuminating wavelength is in the range 500nm to 650nm.
12. A method according to any preceding claim, wherein the wavelength of the illuminating radiation comprises a primary wavelength or narrow wavelength band substantially in the range 570nm to 590nm.
13. A method according to any preceding claim, wherein the energy density of the illuminating radiation is in the range of  $0.5\text{J}/\text{cm}^2$  to  $5\text{J}/\text{cm}^2$ .

14. Apparatus for cosmetic treatment of a skin condition comprising illuminating radiation delivery means for delivering illuminating radiation to a target skin zone or structure.
- 5 15. Apparatus according to claim 14, for cosmetic treatment of Acne Vulgaris.
- 10 16. Apparatus according to claim 14 or 15, arranged to output radiation of a discrete wavelength or narrow primary wavelength band substantially in or about the range 400nm to 1500nm.
- 15 17. Apparatus according to claim 16, arranged to output radiation of a discrete wavelength or narrow primary wavelength band substantially in or about the range 500nm to 650nm.
- 20 18. Apparatus according to claim 17, arranged to output radiation of a discrete wavelength or narrow primary wavelength band substantially in or about the range 570nm to 595nm.
- 25 19. Apparatus according to any of claims 14 to 18, arranged to deliver radiation at an energy density at the skin surface substantially in the range  $0.5\text{J}/\text{cm}^2$  to  $5\text{J}/\text{cm}^2$ .
- 30 20. Apparatus according to claim 19, configured to inhibit output of energies substantially above the range  $0.5\text{J}/\text{cm}^2$  to  $5\text{J}/\text{cm}^2$ .

21. Apparatus according to claim 19 or 20, configured to permit variable selection of energy densities within the range  $0.5\text{J}/\text{cm}^2$  to  $5\text{J}/\text{cm}^2$ .
- 5 22. Apparatus according to any of claims 14 to 21, arranged to deliver illuminating radiation in a pulsed regime.
23. Apparatus according to claim 22, wherein the pulse  
10 duration of the illuminating radiation is substantially in the range  $10\mu\text{s}$  to  $100\text{ms}$ .
24. Apparatus according to claim 23, wherein the pulse  
15 duration of the illuminating radiation is substantially in the range  $50\mu\text{s}$  to  $10\text{ms}$ .
25. A method or apparatus for the manufacture of an agent for the treatment of a skin condition, the agent comprising illuminating radiation active to effect at  
20 the target zone the following interactions:
- (a) a reaction leading to at least partial disabling of the cause of the skin condition; and
  - (b) non-ablative heating of tissue stimulating an inflammatory response to a degree sufficient to  
25 effect collagen production.
26. A method according to claim 25, for the treatment of Acne Vulgaris.



INVESTOR IN PEOPLE

**Application No:** GB 0025639.6  
**Claims searched:** 1-26

**Examiner:** Stephen Quick  
**Date of search:** 1 October 2001

## Patents Act 1977 Search Report under Section 17

### Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R (REHR)

Int Cl (Ed.7): A61N 5/06, 067

Other: Online: EPODOC, JAPIO, WPI

### Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X,E	GB 2356570 A	(WARBURTON ET AL) 30.05.2001, see whole document, especially page 1	1, 14 & 25 at least
X	GB 2336545 A	(O-LYS), see whole document, especially page 1 (last paragraph), page 2 (2nd paragraph) and pages 4 & 5 (bridging paragraph)	1, 14 & 25 at least
X	GB 2272158 A	(TANSUN), "sun tan" apparatus	14 at least
X	EP 0884066 A2	(SLI LICHT-SYSTEME) see whole document, especially page 1 (lines 3-4 & 10-20) and WPI Abstract Accession No 1999-026352/03	1, 14 & 25 at least
X	EP 0159446 A2	(LASERCARE), see page 2 lines 8-14	14 at least
X,E	WO 00/74782 A1	(SLS BIOPHILE) 14.12.2000, see whole document, especially paragraph bridging pages 1 & 2, page 6 (last complete paragraph) and page 8 (line 26)	14 & 25 at least
X	WO 00/32272 A1	(SLI LICHT-SYSTEME) see whole document, especially page 1 (paragraphs 1 & 4-7)	1, 14 & 25 at least

X Document indicating lack of novelty or inventive step  
Y Document indicating lack of inventive step if combined with one or more other documents of same category.  
& Member of the same patent family

A Document indicating technological background and/or state of the art.  
P Document published on or after the declared priority date but before the filing date of this invention.  
E Patent document published on or after, but with priority date earlier than, the filing date of this application.



INVESTOR IN PEOPLE

**Application No:** GB 0025639.6  
**Claims searched:** 1-26

**Examiner:** Stephen Quick  
**Date of search:** 1 October 2001

Category	Identity of document and relevant passage	Relevant to claims
X	WO 98/38933 A1 (NEW STAR LASERS), see whole document, especially pages 5 (last complete paragraph), 7 (lines 26-27), 9 (line 33) & 12 (lines 31-32), and reference to 660 nm light treatment of acne in US5549660 A	1, 14 & 25 at least
X	WO 96/33773 A2 (OLAVESEN), see whole document, especially page 1 (paragraphs 1-3)	1, 14 & 25 at least
X	US 5549660 A (AMRON), see whole document, especially columns 1 (lines 44-58) & 3 (lines 43-46)	14 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

# (12) UK Patent Application (19) GB (11) 2 390 021 (13) A

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**A61N 5/06**

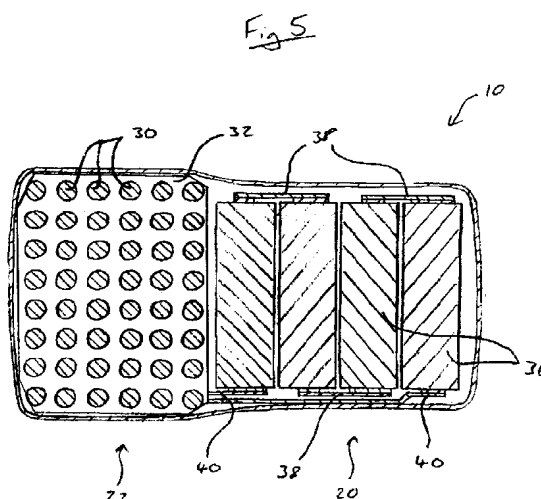
(52) UK CL (Edition V):  
**A5R REHR**

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(58) Field of Search:  
UK CL (Edition V) **A5R REHR**  
INT CL<sup>7</sup> **A61N 5/06**  
Other: **Online databases: Derwent World**  
**Patents Index, Patent Abstracts of Japan and**  
**European Patent Office**

(54) Abstract Title: **HAND-HELD LED APPARATUS FOR TREATING ACNE**

(57) A hand held device 10 for the treatment of acne includes a casing with an operative portion 22, an array of LED's 30 emitting blue light with a peak wavelength of approximately 430nm, which may be parallel arranged, Gallium Nitride LED's mounted on a PCB 32, a handle 20 and batteries 36.



The claims were filed later than the filing date but within the period prescribed by Rule 25(1) of the Patents Rules 1995.

The print reflects an assignment of the application under the provisions of Section 30 of the Patents Act 1977.

GB 2 390 021 A



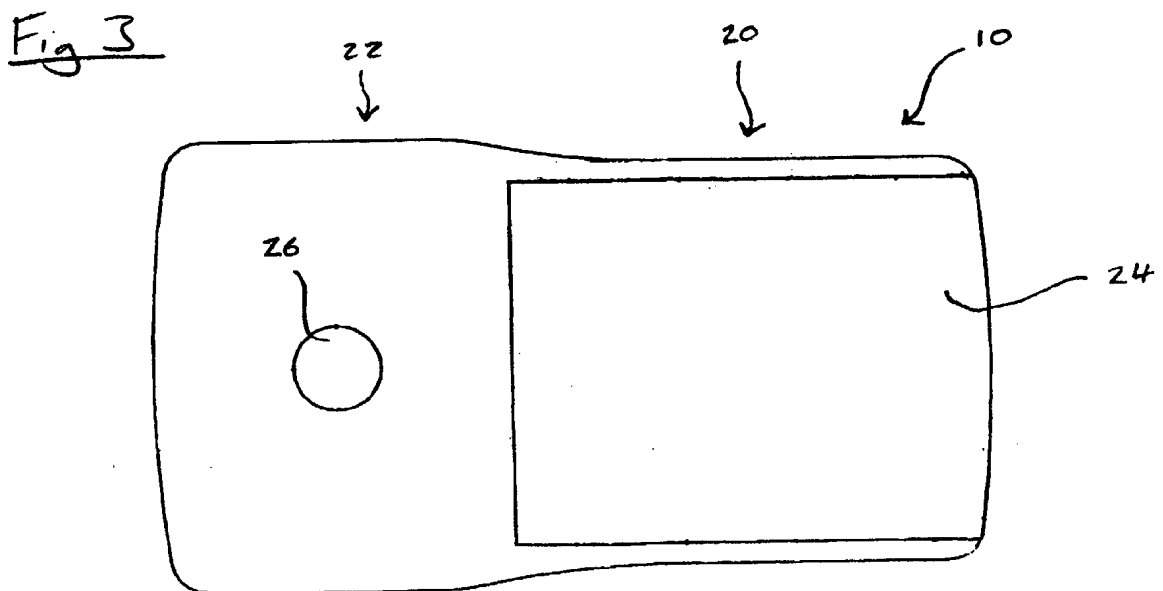
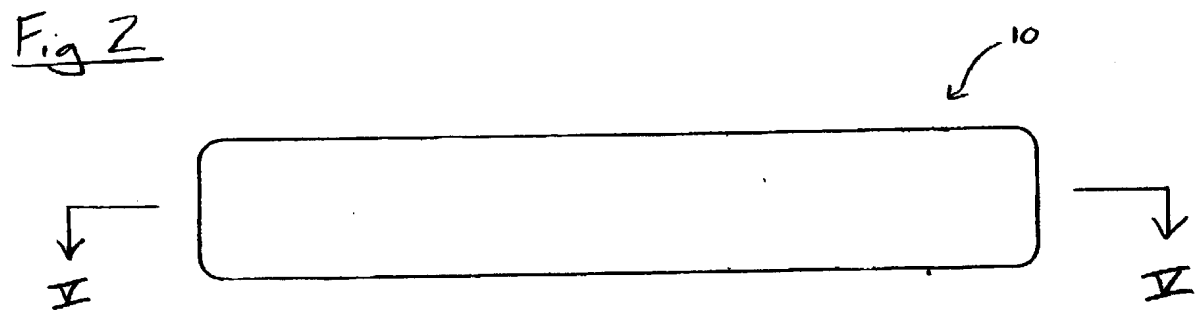
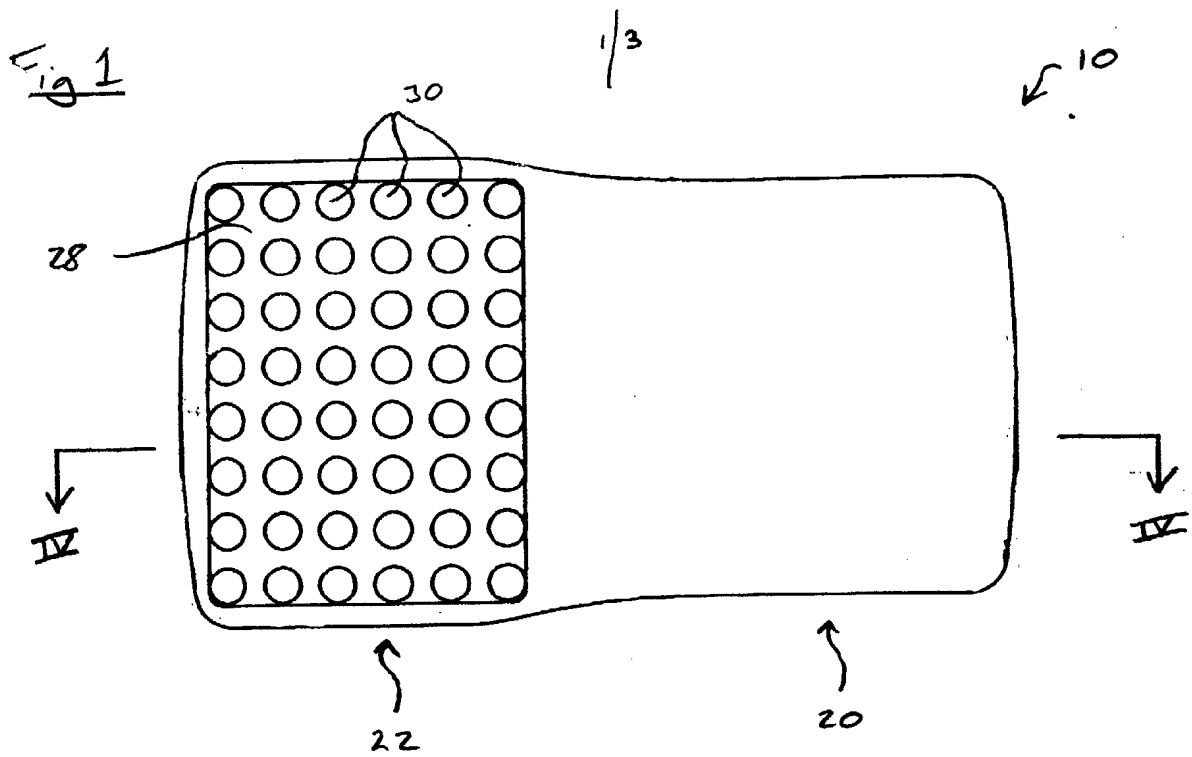


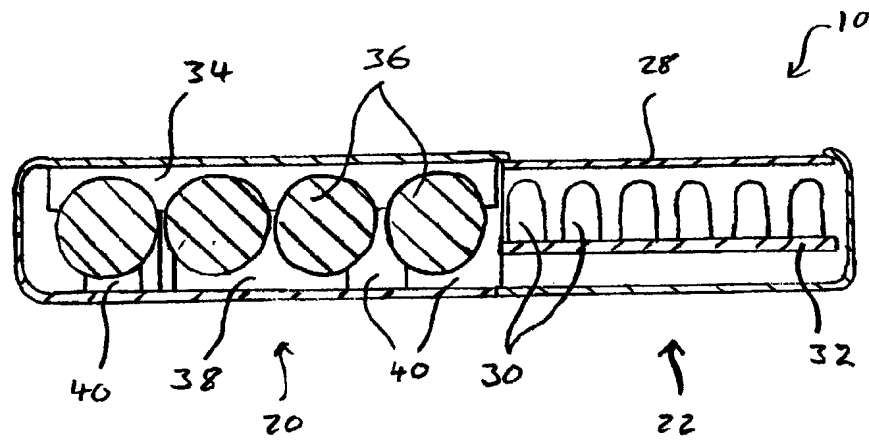
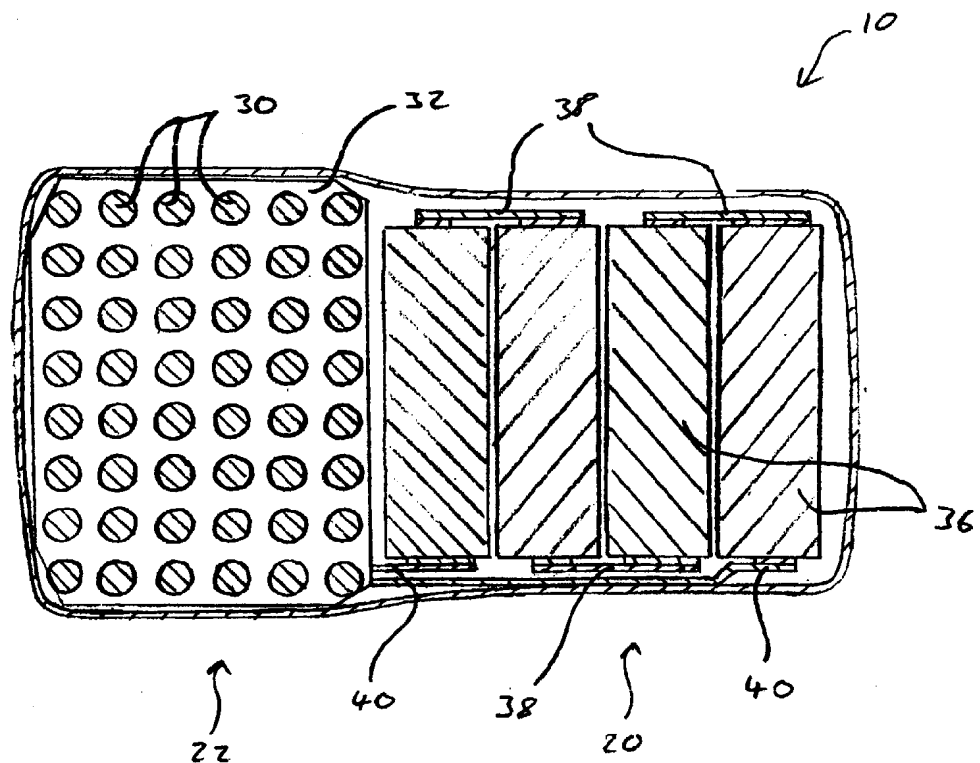
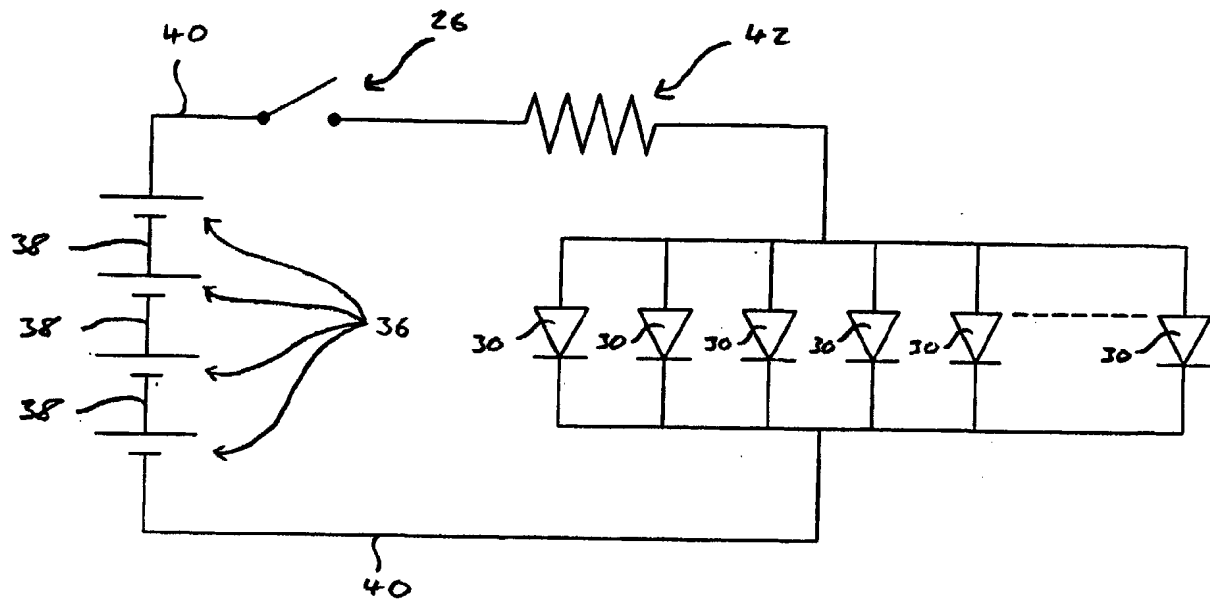
Fig 4Fig 5

Fig 6



Device and Method for Treating Acne

This invention relates to a device and method for treating acne, and in particular a device which uses electromagnetic radiation to treat acne.

5

Acne vulgaris (acne) is a chronic inflammatory condition of the pilosebaceous units of the skin, which is particularly prevalent in adolescents. The condition generally causes the formation, on the skin, of comedones, red papules, pustules and sometimes cysts. This is unsightly and furthermore, if untreated, acne can lead to scarring of the skin. The major causes of acne are thought to be: an increase in sebum production, an increased presence of *propionibacterium acne* (*P. acne*), blockage of the pilosebaceous duct and the production of inflammation.

Conventional treatments for acne include the administering of medicaments such as antibiotics and vitamin A analogue, and the use of topical formulations. Although these treatments are reasonably effective, they can cause unwanted side effects such as skin irritation. In addition, people are often reluctant to use medicaments such as antibiotics over a prolonged period.

Other treatments currently available, include exposing the affected skin to electromagnetic radiation of particular wavelengths. Conventionally, this treatment is carried out in specialised clinics using lasers or fluorescent tubes. A disadvantage of such treatments is that the patient is required to visit the clinic to receive the treatment. The treatment is often relatively intense so that the patient does not have to return too frequently. Such intense treatment may therefore cause damage to the skin, this being a further disadvantage of such treatment.

A major disadvantage of all the above treatments is the cost of maintaining a course of treatment over the many years that acne can persist.

30

There has now been devised a device and method for treating acne, which overcome or substantially mitigate the above-mentioned and/or other disadvantages of the prior art.

- 5 According to the invention, there is provided a handheld device for treating acne comprising an array of light emitting diodes (LEDs) which, in use, emit electromagnetic radiation from the device.

Typically, the electromagnetic radiation has a peak wavelength in the range 330 to  
10 500nm, preferably between 360 and 470nm, more preferably between 390 and 440nm and most preferably between 410 and 430nm.

The array of LEDs may consist of LEDs of a single type, or of two or more different types. Preferably, the LEDs are all of the same type.

15

One type of LED that has been found to be particularly useful in the invention is the gallium nitride (GaN) LED. The device according to the invention thus preferably comprises an array of gallium nitride (GaN) LEDs. A presently preferred GaN LED is that known as BLUELINE Hyper 5mm (T1<sup>3</sup>/<sub>4</sub>) LED, Non  
20 Diffused LB 5416 (sold by Infineon Technologies AG, St.-Martin-Str. 53, 81669 Munich, Germany), which has a peak wavelength of 428nm.

The array of LEDs preferably comprises between 10 and 100 LEDs, most preferably between 35 and 65 LEDs. In use, the LEDs are connected to a power  
25 source, preferably in parallel with each other. The LEDs are preferably arranged in a square or hexagonal array, and are preferably orientated in a similar direction to each other. The LEDs may also have a relatively narrow viewing angle, preferably less than 45° and more preferably less than 20°, so that, in use, as much electromagnetic radiation as possible is directed towards the skin.

30

The device is preferably of a size and shape so as to be easily portable and may include a stand. The power source may be external of the device, such as a mains supply, or enclosed within the device, such as a battery or a series of batteries. Preferably, batteries are received within the device to act as the power  
5 source. The batteries preferably provide each LED with a voltage of between 3 and 9V, for example 6V.

The device preferably comprises a handle portion and an operative portion. The handle portion preferably encloses the batteries. The operative portion preferably  
10 has a window through which the electromagnetic radiation is emitted. The window preferably comprises a sheet of transparent material. The window preferably has dimensions in the range 20 to 100mm and is preferably rectangular.

In use, the device is held by the user, or supported by a stand or the like, in such a  
15 way as to expose the area of skin that is affected by acne to the electromagnetic radiation emitted by the device. The device is typically held between 1 and 15cm away from the skin, more preferably between 2 and 10cm. Each area of skin affected by acne is preferably exposed to the electromagnetic radiation for between 2 and 30 minutes, more preferably between 5 and 15 minutes. The  
20 device is typically used daily.

Thus, according to another aspect of the invention, there is provided a method of improving the appearance of a person's skin, which method comprises positioning  
25 a device as described above in proximity to an area of the skin and actuating the device so as to irradiate the skin with electromagnetic radiation.

The invention will now be described in greater detail, by way of example only, with reference to the accompanying drawings, in which

30 Figure 1 is a plan view of a device according to the present invention;

Figure 2 is a side view of the device;

Figure 3 is an underside view of the device;

5 Figure 4 is a sectional view of the device along the line IV-IV in Figure 1;

Figure 5 is a sectional view of the device along the line V-V in Figure 2; and

Figure 6 is a schematic circuit diagram of the device.

10

Referring firstly to Figures 1, 2 and 3, a device according to the present invention is generally designated 10. The device 10 comprises a casing having a handle portion 20 and an operative portion 22. The device 10 is generally rectangular in shape but with the width of the handle portion 20 being less than that of the  
15 operative portion 30. The device 10 is approximately 115mm in length, 65mm in width and 20mm in depth. The casing may be of any suitable material but a plastics material is preferable. Typically, the casing comprises a pair of cooperating components, each injection-moulded in plastics material.

20 The lower surface of the casing has a removable panel 24 extending across the entire length and the majority of the width of the handle portion 20. The removable panel 24 also extends a certain distance along the end face of the handle portion 20. The lower surface of the casing further includes an on/off switch 26, which is situated within a circular aperture in the centre of the operative portion 22.

25

The upper surface of the casing has a rectangular opening extending across the majority of the width and length of the operative portion 22. Affixed to the interior of the casing, immediately behind this opening, is a transparent sheet 28 of slightly greater dimensions than the opening. The opening and transparent sheet 28  
30 therefore form a window into the device 10. Behind the transparent sheet 28, mounted within the casing, is a PCB 32 (shown in Figure 4) having a regular array

of forty-eight light emitting diodes (LEDs) 30 mounted on its upper surface and arranged in six rows of eight.

5 The LEDs 30 are all GaN LEDs which emit electromagnetic radiation over a range of wavelengths including the range 407 to 420nm, and with a peak wavelength of approximately 430nm. The presently preferred LED is that referred to as BLUELINE Hyper 5mm (T1<sup>3</sup>/<sub>4</sub>) LED, Non Diffused LB 5416 (sold by Infineon Technologies AG, St.-Martin-Str. 53, 81669 Munich, Germany), which has a peak wavelength of 428nm.

10

Turning now to Figure 4, the upper interior surface of the device 10 is formed with two downwardly extending skirts 34 (only one being visible in Figure 4), each having four semi-circular recesses. With the removable panel 24 temporarily removed, a battery 36 may be received within each pair of corresponding recesses  
15 in the two skirts 34.

Turning now to Figure 5, the device further includes connectors 38 which are strips of metal mounted within the casing. The connectors 38 connect the ends of each battery 36 so that the batteries 36 are connected in series. Connectors 40 then  
20 connect each end of the series of batteries 36 to the PCB 32.

Turning now to Figure 6, the device further includes a resistor 42, mounted on the PCB 32. The batteries 36, the connectors 38 and 40, the switch 26, the resistor 42 and the LEDs 30 are connected together as shown in Figure 6. The LEDs 30  
25 being in parallel and the other components being in series with each LED 30.

In use, the on/off switch 26 is pressed by the user to activate the array of LEDs 30. The device 10 is then held by the user in such a way as to expose the area of skin that is affected by acne to the electromagnetic radiation emitted by the LEDs 30.  
30 The device 10 is typically held a few centimetres away from the skin. This exposure is continued for a length of time, typically 10 minutes. Other areas of



skin affected by acne may then be exposed for a similar length of time. The on/off switch is pressed to deactivate the LEDs 30 after use. The above treatment is typically performed daily.

## Claims

What is claimed:

1. An apparatus for the cosmetic treatment of acne vulgaris, the apparatus comprising of a housing and an array of LEDs disposed within the housing for irradiating affected skin areas with light in the blue region with a peak wavelength of 430nm.
2. The apparatus according to claim 1, wherein the LED's are arranged substantially parallel to each other.
3. The process according to claim 1 wherein the irradiating step is conducted once per day for about 10 minutes.
4. The apparatus according to claim 1 wherein the apparatus is hand held.
5. The process according to claim 1 wherein the apparatus is held no more than 10mm from the surface of the skin to be treated.
6. The process according to claim 1 wherein the apparatus can be held directly onto the skin.
7. The apparatus according to claim 1 wherein the LED's are arranged in a cluster of 48 LED's.
8. The apparatus according to claim 1 wherein the apparatus has a low power output where the luminous intensity of a single LED is typically 65mcd at 20mA.
9. The apparatus according to claim 1 wherein the apparatus is safe for home use by the end user.
10. The apparatus according to claim 1 wherein the apparatus can be used without medical supervision.



INVESTOR IN PEOPLE

**Application No:** GB 0211272.0  
**Claims searched:** 1 to 10

**Examiner:** Karl Whitfield  
**Date of search:** 23 October 2003

## Patents Act 1977 : Search Report under Section 17

### Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1-10	GB 2356570 A	(WARBURTON) see abstract & claim 17
X, Y	X: 1-3 & 5-8 Y: 4	WO 00/44441 A1	(BIOLIGHT) see page 5 lines 30-34
X, Y	1-3 & 5-8 Y: 4	WO 00/43068 A1	(BIOLIGHT) see page 5 lines 14-18
X, Y	X: 1-3, 7 & 8 Y: 4-6, 9 & 10	WO 00/02491 A1	(HARTH et al.) see especially fig 4
X	1-10	WO 95/26217 A1	(MAEF) see especially page 5 & fig 2
A	1-3, 6 & 8-10	US 2003/0009158 A1	(PERRICONE) see abstract
A	1-3, 7 & 8	US 2002/0173833 A1	(KORMAN et al.) see especially fig 4
A	1-3, 7 & 8	US 2002/0128695 A1	(HARTH et al.) see especially fig 4
X, Y	X: 1-3, 7 & 8 Y: 4-6, 9 & 10	US 2001/0023363 A1	(HARTH et al.) see especially fig 4
X, Y	X: 1-3 & 5-10 Y: 4	US 6524329	(BENEDICT) see fig 3 & col 2
Y	4-6, 9 & 10	US 6019482	(EVERETT) whole document

### Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

# (12) UK Patent Application (19) GB (11) 2 397 528 (13) A

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**US 20020161418 A**

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INT CL<sup>7</sup> **A61N 5/06**  
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(54) Abstract Title: **Apparatus and method for treatment of skin conditions**

(57) A method and apparatus for improving the cosmetic appearance of a region of skin 11 affected by Acne Vulgaris, Rosacea or similar skin condition by means of directing light radiation 12 from an illuminating device 1 on to the skin 11. The apparatus 10 comprises a control unit 9 that operates one or more LEDs 7 (light emitting diodes) of the illuminating device 1. Each dose of light radiation 12 lasts for at least 100ms, during which time the skin 11 receives light energy from the LED(s) 7, which causes a photochemical reaction that stimulates the production of free radicals (singlet oxygen) that react with, and at least partially disable or destroy, bacteria that contribute to the symptoms of the skin condition. The light energy directed on to the skin 11 during any given period of 10 $\mu$ s is less than 0.5 Jcm<sup>-2</sup>, and during any given period of 100ms is less than 5 Jcm<sup>-2</sup>. Substantially no beneficial photo-thermal reaction occurs within the skin 11. Light having wavelengths around 405nm and/or 585nm is used. The duration of a single dose may be much longer than 100ms and can last up to 10 hours (for overnight treatment).

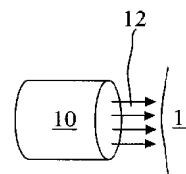


Fig 1

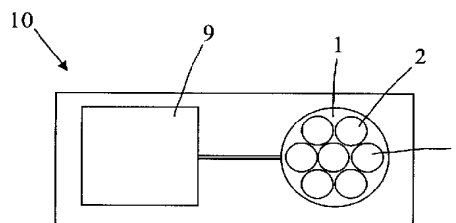


Fig 2

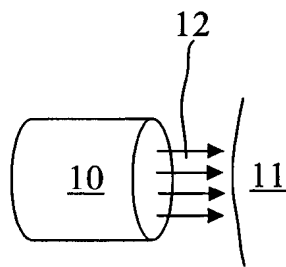


Fig 1

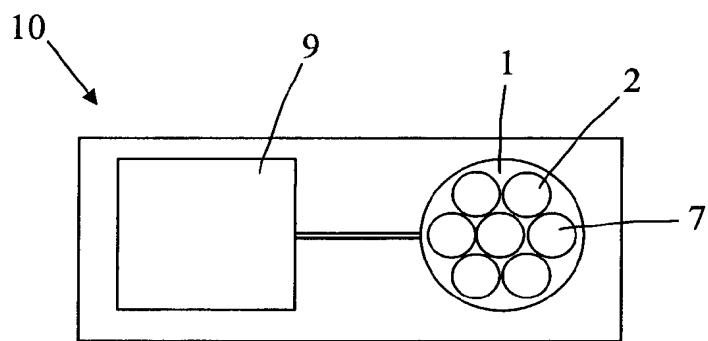


Fig 2

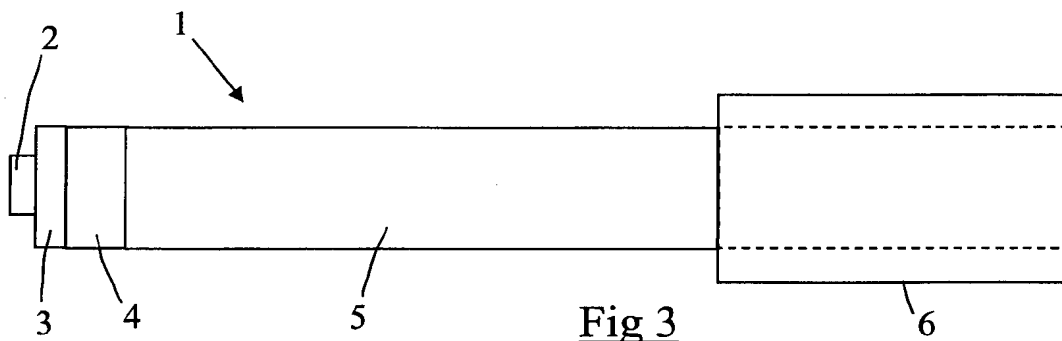


Fig 3

Apparatus and method for treatment of skin conditions

5 The present invention relates to an apparatus and method for the cosmetic treatment of a skin condition. In particular, the invention relates to an apparatus and a non-surgical method for the cosmetic treatment of Acne Vulgaris.

Acne Vulgaris is a skin condition which affects almost 100% of the population at some point in their lives. It is a  
10 condition of the sebaceous follicles (pores) and can lead to lesions on the skin, primarily on the face, shoulders and back. The symptoms of Acne Vulgaris, and of other similar skin conditions, can be unsightly and undesirable cosmetically.

Acne Vulgaris is caused by a number of factors, of which the  
15 most significant are believed to be: excessive hormone production (especially androgens), excessive sebum production (sebum is an oily substance produced by the sebaceous glands to keep the skin soft, pliable and waterproof), excessive dead cell shedding, the presence of bacteria (particularly *Propionibacterium acnes*) in  
20 the sebaceous follicles and the bodies inflammatory response (chemotaxis).

The process starts when dead skin cells and the oily substance sebum combine to block the skin's sebaceous follicles. The dead skin and sebum form a plug which traps oil and bacteria  
25 within the sebaceous follicles. The sebaceous follicle begins to swell as the as the skin continues its normal oil production. Normal skin bacteria *Propionibacterium acnes* multiply rapidly in the clogged pore. The multiplication of the bacteria produces substances which cause inflammation in the follicle and  
30 surrounding skin. The body's response is to send white blood cells to the inflamed areas.

The lesions range in severity and can be defined as comedones, papules, nodules, pustules and cysts. Comedones are

sebaceous follicles that have become blocked. Papules are small (less than 5mm) solid lesions slightly above the surface of the skin. Nodules are larger papules (greater than 5mm). Pustules are dome shaped fragile lesions typically containing a mixture of white blood cells, dead cells and bacteria. Cysts are similar to pustules but are larger and are severely inflamed and often lead to scarring.

Various drug treatments are known to be at least partially effective in preventing Acne Vulgaris.

A treatment for Acne Vulgaris using light radiation is disclosed in GB 2 368 020. In the embodiments disclosed, radiation is provided at specific energy densities and wavelengths in order to cause photo-chemical and photo-thermal reactions in the skin. The photo-chemical reaction leads to a partial disabling or eradication of a cause of the skin condition while the photo-thermal reaction increases collagen production, thereby helping to reduce the risk of scarring.

The method disclosed in GB 2 368 020 requires the provision of relatively high doses of radiation ( $0.5\text{Jcm}^{-2}$  to  $5\text{Jcm}^{-2}$ ) in short periods of time (10 $\mu\text{s}$  to 100ms) in order to produce the photo-thermal effects in the skin. Providing these high energy levels over short periods of time requires high power lasers. These are expensive to manufacture and operators may be required to have specialist training and knowledge to use them safely and effectively.

It is an object of the invention to provide an apparatus for improving the appearance of the skin, for example an apparatus for the treatment of a skin condition, that is relatively inexpensive and/or simple to operate. It is an alternative or additional object of the invention to provide a method for improving the appearance of the skin or for the cosmetic

treatment of a skin condition that is relatively inexpensive and/or simple to carry out.

According to one aspect of the invention there is provided an apparatus for the treatment of a skin condition comprising

5 an illuminating device, and

a control unit for controlling the operation of the illuminating device, wherein

the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and  
10 wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by the skin condition, which reaction would result in agents causing the skin condition being at least partially disabled or destroyed, and

the control unit and illuminating device are so arranged and  
15 configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

the light energy received at said area during a period of at  
20 least 100ms is at least  $0.01 \text{ Jcm}^{-2}$ ,

the light energy received at said area in any given period of  $10\mu\text{s}$  is less than  $0.5 \text{ Jcm}^{-2}$ , and

the light energy so delivered in any given period of 100ms is less than  $5 \text{ Jcm}^{-2}$ , whereby

25 the apparatus may be used to treat the skin condition.

According to another aspect of the invention there is provided an apparatus for improving the cosmetic appearance of the skin of a mammal, the apparatus comprising

an illuminating device for emitting light radiation, and

30 a control unit for controlling the operation of the illuminating device, wherein



the control unit is so arranged and configured that it is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

5       the light energy received at said area during a period of at least 100ms is at least  $0.01\text{Jcm}^{-2}$ ,

the light energy received at said area in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ , and

10       the light energy so delivered in any given period of 100ms is less than  $5\text{Jcm}^{-2}$ , whereby

the apparatus may be used to improve the cosmetic appearance of the skin. The illuminating device may be so arranged and configured that it is able, when being used to direct light onto the skin, to emit light radiation of an energy and wavelength  
15       profile sufficient to cause a photochemical reaction within an area of the skin being targeted. The photochemical reaction may be caused in such a way that it partially disables or destroys agents in the skin that are causing the cosmetic appearance of the skin to be worsened.

20       Further optional or preferred features of the apparatus according to either of the above-mentioned aspects of the invention are described below.

The illuminating device preferably comprises one or more light emitting semiconductor devices. The or each semiconductor  
25       device may be in the form of a diode. The illuminating device may for example comprise one or more LEDs. LEDs are, advantageously relatively inexpensive and simple to operate in comparison to lasers. Laser diodes may additionally or alternatively be used. Conveniently, the illuminating device is  
30       in the form of a device, for example comprising at least one semiconductor device that in use acts as the active light

emitting element(s), that has a power input requirement of less than 500W, and preferably less than 100W, per individual semiconductor device.

5 The control unit and illuminating device of the apparatus may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver light energy of between 0.01 and 100 Jcm<sup>-2</sup> to said area during a period of between 200ms and 3 seconds, or more preferably during a period of between 300ms and 2 seconds. Of course, the control unit and  
10 illuminating device may be arranged to emit radiation during a single treatment over a longer period of time, so that during a single treatment more than 100 Jcm<sup>-2</sup> is delivered over a period of greater than 3 seconds. A single treatment might last as long as up to 10 hours. Such a treatment might for example be  
15 provided overnight. Preferably, the control unit and illuminating device of the apparatus are so configured and arranged that less than 100 Jcm<sup>-2</sup> of light energy is delivered during any period of 3 seconds.

The control unit and illuminating device may be so  
20 configured and arranged that the illuminating device delivers pulsed light radiation during a single treatment. Alternatively, the control unit and illuminating device may be so configured and arranged that the illuminating device delivers continuous light radiation during a single treatment. The apparatus may be so  
25 configured to be able to deliver either continuous or pulsed radiation at the choice of the user.

The control unit and illuminating device of the apparatus may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver light energy  
30 of between 0.5 Jcm<sup>-2</sup> and 3 Jcm<sup>-2</sup> to said area during a period of between 100ms and 100 seconds. The control unit and illuminating device may be so configured and arranged that the control unit is

able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10 seconds (or more preferably between 200ms and 3 seconds) and the energy of the light radiation delivered during the single dose being greater than  $0.1 \text{ Jcm}^{-2}$  and being equal to  $T_1 \times P_1$ , where  $T_1$  = the length in time of the single dose and  $P_1$  has the units of optical power density (power per unit area) and satisfies  $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$ .

The apparatus may be in the form of a top up apparatus allowing lower levels of light energy to be delivered. For example, the control unit and illuminating device may be so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 300ms and 10 seconds (or more preferably between 300ms and 3 seconds) and the energy of the light radiation delivered during the single dose being equal to  $T_2 \times P_2$ , where  $T_2$  = the length in time of the single dose and  $P_2$  has the units of optical power density (power per unit area) and satisfies  $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$ .  $P_2$  may satisfy the condition  $0.1 \text{ Wcm}^{-2} < P_2 < 0.5 \text{ Wcm}^{-2}$ .

The apparatus may be so configured and arranged that it is suitable for treatment of relatively small areas at a time. For example, the apparatus may be so configured and arranged that, during a single dose of light radiation, an area of skin of between  $12$  and  $200 \text{ mm}^2$  is treated.

The apparatus may be so configured and arranged that it is suitable for lower power operation over longer periods of time. For example, the control unit and illuminating device may be so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10

hours (more preferably between 10 seconds and 8 hours), light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than  $0.1 \text{ Jcm}^{-2}$  and being equal to  $T_3 \times P_3$ , where  $T_3$  = the length in time of the single treatment and  $P_3$  has the units of optical power density (power per unit area) and satisfies  $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$ . The longer treatment may last for at least 30 seconds, preferably lasts for at least 10 minutes and more preferably lasts for at least an hour.

The apparatus may be so configured and arranged that it is suitable for treatment of relatively large areas at a time. For example, the apparatus may be so configured and arranged that, during a single treatment, an area of skin of between  $0.003 \text{ m}^2$  and  $0.5 \text{ m}^2$  is treated. Such an apparatus is preferably arranged such that the energy of the light radiation delivered during a single treatment is equal to  $T_3 \times P_3$ , where  $T_3$  = the length in time of the single treatment and  $P_3$  has the units of optical power density (power per unit area) and satisfies  $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$ .

The illuminating device is preferably arranged to provide light radiation including radiation having a wavelength of between 350nm and 1500nm. The illuminating device is preferably arranged to emit radiation at a wavelength between 350nm and 1000nm, more preferably between 350nm and 700nm. The illuminating device is preferably arranged to provide light radiation including radiation having a wavelength between 570nm and 600nm. The illuminating device may alternatively or additionally be arranged to provide light radiation of a wavelength between 390nm and 420nm, and preferably includes light radiation having a wavelength of about 405nm.

The photo-chemical reaction that may be caused by the apparatus when used to treat the skin may take place in Porphyrin,

which is a naturally occurring substance produced by the bacteria *Propionibacterium acnes*. Further discussion is provided below in relation to a method according to another aspect of the invention. The Porphyrin activation spectrum has peaks at both about 585nm  
5 and 405nm. Providing light radiation including light having a wavelength between 390nm and 420nm and including light having a wavelength between 570nm and 600nm is considered to be particularly advantageous as such a combination may activate Porphyrin at different depths in the skin tissue.

10 Also, it is believed that red light (of a wavelength between 630nm and 680nm) may aid in the wound healing process.

The illuminating device is preferably arranged to provide light radiation having a peak power level of less than  $100\text{Wcm}^{-2}$ . More preferably, the illuminating device is preferably arranged  
15 to provide light radiation having a peak power level of less than  $10\text{Wcm}^{-2}$ . Even more preferably, the illuminating device is preferably arranged to provide light radiation having a peak power level of less than  $5\text{Wcm}^{-2}$ . Advantageously, the peak power level is between about  $1\text{Wcm}^{-2}$  and  $5\text{Wcm}^{-2}$ . The peak power level  
20 may be between about  $1\text{Wcm}^{-2}$  and  $3\text{Wcm}^{-2}$ .

The apparatus may include cooling means for controlling the temperature of the illuminating device. The control unit is preferably arranged to control operation of any such cooling means. The control unit may conveniently comprise a suitably  
25 pre-programmed microprocessor.

In accordance with the present invention there is also provided a use of said apparatus including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an energy such that an area of at least  
30  $12\text{mm}^2$  receives energy from the illuminating device during a period of at least 100ms of at least  $0.01\text{Jcm}^{-2}$ , the radiation including radiation having a wavelength of between 350 and 700nm

(preferably including radiation having a wavelength of between 570 nm and 600 nm and/or of between 390nm and 420nm), the energy received from the illuminating device at said area in any given period of 10 $\mu$ s being less than 0.5 Jcm<sup>-2</sup>, and the energy received  
5 from the illuminating device in any given period of 100ms being less than 5 Jcm<sup>-2</sup>. Said use is advantageously, but not necessarily, performed to treat a skin condition on the skin of a human. The use of the apparatus may for example be in the form of performing a method of improving the cosmetic appearance of  
10 the skin and/or a method of cosmetic treatment of a skin condition. The use of the apparatus may for example be in the form of testing and/or demonstrating the apparatus on a surface that is, for example, not in the form of the skin of a living animal or human.

15 The apparatus of the invention is advantageously so arranged that the apparatus may be used to treat the skin of a patient without the need to pre-cool the skin before treatment.

According to another aspect of the invention there is provided a method for the treatment of a skin condition  
20 comprising the steps of

providing an illuminating device, and  
operating the illuminating device to direct light radiation on to an area of skin affected by the skin condition, wherein  
during a single treatment, lasting at least 100ms, said area  
25 receives light energy from the illuminating device of at least 0.01Jcm<sup>-2</sup>,

the light energy so delivered in any given period of 10 $\mu$ s is less than 0.5 Jcm<sup>-2</sup>,

the light energy so delivered in any given period of 100ms  
30 is less than 5 Jcm<sup>-2</sup>, and

the light energy so delivered causes a photochemical reaction within the affected skin which at least partially disables or destroys agents causing the skin condition.

There is also provided according to another aspect of the invention a method of improving the cosmetic appearance of a region of the skin, for example of a mammal, comprising the steps of

providing an illuminating device, and  
operating the illuminating device to direct light radiation on to the region of skin, wherein

during a period of at least 100ms, said region receives light energy from the illuminating device of at least  $0.01\text{Jcm}^{-2}$ ,

the light energy so delivered in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ , and

the light energy so delivered in any given period of 100ms is less than  $5\text{Jcm}^{-2}$ .

There is also provided a method for the cosmetic treatment of Acne Vulgaris comprising the steps of

providing an illuminating device, and  
operating the illuminating device to direct light radiation on to an area of skin affected by Acne Vulgaris, wherein

during a single treatment, lasting at least 100ms, said area receives light energy from the illuminating device of at least  $0.01\text{Jcm}^{-2}$ ,

the light energy so delivered in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ ,

the light energy so delivered in any given period of 100ms is less than  $5\text{Jcm}^{-2}$ , and

the light energy so delivered causes a photochemical reaction within the affected skin which at least partially

disables or destroys bacteria contributing to the symptoms of Acne Vulgaris.

5 The light energy so delivered advantageously causes a photochemical reaction within the skin. The method may be non-therapeutic. In particular, the illuminating device may be operated in such a way as to cause no therapeutic effect on the region of skin. Conducting the method may however result in the cosmetic appearance of the affected area of skin being improved.

10 By providing direct light radiation for a longer period of time than prior art methods, similar photon or energy densities can be delivered but at much lower power densities or energy flux densities, thereby reducing the likelihood of any adverse reactions of the skin to the radiation, for example, causing photo-mechanical effects (explosive expansion of the tissue) or  
15 photo-thermal effects (rapid heating of the tissue). In addition, providing radiation at lower power means the radiation is less likely to induce erythema (redness of the skin). Advantageously, the method of the invention is performed without any active pre-cooling of the skin immediately before treatment. Some prior art  
20 methods utilising higher light intensities than in the present invention cause the target area to be heated so quickly that heat cannot be effectively dissipated by means of the vascular system, such methods thus requiring cooling of the skin before treatment to prevent undesirable effects associated with the over-heating  
25 of the skin.

Preferably, during said period of at least 100ms, said region receives light energy from the illuminating device of less than  $10\text{kJcm}^{-2}$ , and more preferably less than  $1\text{kJcm}^{-2}$ . Preferably, during said period of at least 100ms, no more than  $100\text{Jcm}^{-2}$  of  
30 light energy is delivered over any given period of 1 minute. The method may be so performed that during said period of at least 100ms, no more than  $100\text{Jcm}^{-2}$  of light energy is delivered over



any given period of 10 minutes. The light energy so delivered in any given period of 1ms is preferably less than  $1\text{Jcm}^{-2}$ . The light energy so delivered in any given period of 10ms is preferably less than  $1\text{Jcm}^{-2}$ . The light energy so delivered in  
5 any given period of  $500\mu\text{s}$  is preferably less than  $1\text{Jcm}^{-2}$ . Said period is preferably less than 10 hours.

The light energy so delivered in any given period of  $10\mu\text{s}$  is preferably less than  $50\text{mJcm}^{-2}$ , more preferably is less than  $10\text{mJcm}^{-2}$ , and yet more preferably is less than  $5\text{mJcm}^{-2}$ . The light  
10 energy so delivered in any given period of  $10\mu\text{s}$  may be less than  $1\text{mJcm}^{-2}$ .

The lower power requirements of the present invention compared to prior art methods means that LEDs (Light Emitting Diodes) can be used rather than lasers. At low powers, these  
15 tend to be cheaper and less complicated than equivalent laser systems. Also the use of laser devices is in many countries subject to strict regulations. The illuminating device thus advantageously includes a plurality of LEDs, for example, including a plurality of LEDs grouped together to form an array.  
20 A single LED may be used. For example, the LEDs may form a 1 dimensional line array or a 2 dimensional array suitable for illumination of larger areas such as the face or back. Advantageously, the LEDs could be grouped to form a face mask under which a user (i.e. a person whose skin is affected by a  
25 skin condition) could be positioned. Using such a face mask system enables a substantially uniform dose of radiation to be applied to the whole face within a short amount of time, for example in a period as short as 30 seconds. In contrast, it can take up to 30 minutes for an operator to treat a whole face using  
30 the single spot applicator system. In both cases, the skin would

receive a similar dose of light radiation to induce a similar photochemical response.

The method may be utilised in a method of therapeutic treatment on the human body. The method may alternatively be  
5 non-therapeutic, in that the method does not treat a skin disease; rather, the method treats a skin condition. The method may be in the form of a method of cosmetic treatment.

The method is preferably for the cosmetic treatment of Acne Vulgaris. The method may be in the form of a method for the  
10 cosmetic treatment of Rosacea.

The "skin" referred to may be the skin of a mammalian animal, preferably human. The method is advantageously non-surgical. For example, the illuminating device is preferably arranged and configured so as to be unable to be operated at sufficiently high  
15 power to be considered a surgical device necessitating a skilled operator, such as a surgeon. Such features provide a key advantage in that the illuminating device may thus be arranged to be intrinsically more safe and less complex to operate and manufacture than the pulsed dye laser of apparatuses of the prior  
20 art.

Performance of the method may cause a photo-chemical reaction in the skin that disables or destroys, wholly or partially, the bacteria *Propionibacterium acnes*, which, as described above, is one of the causes of Acne Vulgaris.  
25 *Propionibacterium acnes* is anaerobic and is harmed by the presence of oxygen. The photo-chemical reaction may be such that the symptoms of acne are, at least temporarily, reduced without permanently destroying the agents, for example the bacteria, that contribute to the symptoms of a skin condition.

30 The photo-chemical reaction may take place in a substance as a result of that substance absorbing radiation within a range of particular wavelengths (the reaction being significantly slower

or non-existent outside the range). Preferably the wavelength of radiation used produces a photo-chemical reaction in a substance (a chromophore, for example) of, on or in the skin that results in the production of free radicals (for example in the form of oxygen singlets) which thereafter may destroy the bacterium. The chromophore targeted is preferably Porphyrin. Porphyrin is a naturally occurring substance produced by the bacteria *Propionibacterium acnes*. Porphyrin produces singlet oxygen when excited by light of a wavelength of around 585nm (yellow light) and also when excited by light of a wavelength of around 405nm (violet/near ultra-violet light). Light at other wavelengths is also able to stimulate free-radical production.

Thus by exciting Porphyrin in the manner outlined above it is possible to disable or destroy the bacterium responsible for *Acne Vulgaris* in a pain-free, non-invasive and efficient manner. The method according to the present invention provides a means of destroying, at least partially, the bacteria that contributes to a skin condition but without needing to use high power lasers, which as mentioned above have various disadvantages.

The duration of the treatment or the length of the period during which light radiation is provided by the illuminating device may, for example, be between 100ms and 30 minutes, is preferably between 200ms and 10 seconds, is more preferably between 200ms and 3 seconds and is yet more preferably between 300ms and 2 seconds. The duration or period may alternatively or additionally be greater than 500ms. The delivery of light radiation may be continuous during a single treatment or during said period. Alternatively, the delivery of light radiation may be pulsed during a single treatment or during said period.

The duration of the light radiation is preferably substantially greater than the thermal relaxation time of the microvascular system near the area of skin affected by the skin

condition. Thus, the photo-thermal response taught in GB2368020 is not significant in the proposed method due to the relatively low dose of light radiation energy supplied within the hundreds of micro-seconds timescale (of the same order of time as that of the microvascular thermal relaxation timescale).

The energy density of the illuminating radiation delivered may, for example, be between  $0.01$  and  $100 \text{ Jcm}^{-2}$ , is preferably between  $0.1$  and  $10 \text{ Jcm}^{-2}$ , is more preferably between  $0.5$  and  $3 \text{ Jcm}^{-2}$  and is even more preferably between  $1$  and  $3 \text{ Jcm}^{-2}$ . The energy density may be less than  $2 \text{ Jcm}^{-2}$ . Lower energy densities are preferable at longer durations.

The dominant wavelength of the illuminating radiation is preferably pre-determined. The radiation may, for example, include radiation having a wavelength of between  $350\text{nm}$  and  $1500\text{nm}$ , or more preferably between  $350\text{nm}$  and  $1000\text{nm}$ . The wavelength is preferably between  $350\text{nm}$  and  $700\text{nm}$ , more preferably between  $570\text{nm}$  and  $600\text{nm}$  and is even more preferably between  $580\text{nm}$  and  $590\text{nm}$ . The illuminating radiation may include radiation substantially concentrated around the wavelength of yellow light ( $585\text{nm}$ ). The radiation may include radiation having a wavelength of between  $350\text{nm}$  and  $450\text{nm}$ , or more preferably between  $390\text{nm}$  and  $420\text{nm}$ . The illuminating radiation may include radiation substantially concentrated around the wavelength of violet/near ultra-violet light ( $405\text{nm}$ ). In accordance with the invention, especially insofar as the treatment for Acne Vulgaris is concerned, the radiation may be chosen to correspond to a photosensitizer such as for example porphyrin in skin tissue. The wavelength of the light radiation may be chosen to correspond with a wavelength suitable for targeting the porphyrin in the skin layers at a depth suitable to ensure that singlet oxygen is released which affects the propionibacterium Acnes without significantly affecting other tissues.

It is especially advantageous to use radiation at one or more wavelengths that correspond to one or more of the peaks of the porphyrin absorption curve.

5 The illuminating radiation may be provided to an area of the affected skin of between 12 and 200mm<sup>2</sup>, for example, to a spot size of diameter 4-16mm. The area may be less than 100mm<sup>2</sup>. A greater area may be treated however. For example an area of up to 0.1m<sup>2</sup> or even up to 0.5m<sup>2</sup> might be treated simultaneously.

10 Preferably the illuminating radiation delivered has a peak optical power level of less than 100Wcm<sup>-2</sup> and more preferably less than 10W cm<sup>-2</sup>. The illuminating radiation preferably provides a peak optical output power level of between 1 and 5Wcm<sup>-2</sup>.

15 The light energy so delivered by the illuminating device may cause a photochemical reaction within the affected skin thereby stimulating the production of free-radicals, which react with, and at least partially disable or destroy, agents causing the skin condition.

20 A low power spot or line treatment may be used to "top up" the higher dose treatment described above. The top up treatment may for example be provided at lower powers than the higher dose treatment and over longer periods of time (for example, overnight). Such a low power treatment might be particularly well suited to use of the illuminating device in the home.

25 The method is preferably performed such that the distance between the illuminating device and the surface onto which the radiation is delivered is less than 1000mm, and is preferably less than 100mm. The distance of separation may be less than 50mm. The illuminating device and the surface may be directly adjacent to each other and may for example touch when radiation  
30 is being delivered.

Above, mention is made of light energy causing a photochemical reaction within the skin. In order to cause a photochemical reaction in the skin, it is believed that the extent/amount of the photochemical reaction depends primarily on the amount of light (i.e. number of photons) received per unit area and that the power of light used has a lesser effect.

According to certain embodiments of the invention, it is preferred for the light energy to be delivered over a relatively long period of time. According to certain other embodiments of the invention, it is preferred for the light energy to be delivered over a relatively short time without exceeding a given power level that might cause undesirable effects resulting from heating of the skin. Thus according to some aspects of the invention it is preferred to have as high a power output as is reasonably possible without exceeding a maximum power output, above which there would be a risk of causing such undesirable effects. It is considered especially advantageous that the present invention is able to provide an apparatus that utilises semiconductor light emitting devices (such as LEDs or laser diodes) that are able to operate at such power levels.

It will be appreciated that the method of the invention may include use of the apparatus of the invention and that the apparatus of the invention may be arranged and configured to be suitable for performing the method of the invention. Thus, features described with reference to the method of the invention may be incorporated in the apparatus of the invention. Also, features described with reference to the apparatus of the invention may be incorporated in the method of the invention.

An embodiment of the present invention will now be described by way of example with reference to the following schematic drawings of which:

Figure 1 shows an apparatus including a control unit and an illuminating device being used to treat the skin of a patient;

Figure 2 shows the control unit and illuminating device of the apparatus shown in Figure 1; and

Figure 3 shows in greater detail the illuminating device of the apparatus shown in Figure 1.

Figure 1 shows an apparatus 10 for the treatment of a skin condition such as acne by directing light radiation 12 onto the skin 11 of a human patient. The skin to be treated in this embodiment is an area of skin on the face including a spot having a diameter about 6mm. The apparatus 10, in this embodiment a hand-held battery powered unit, includes an illuminating device 1 and a control unit 9 linked thereto which controls the radiation emitted by the device 1. The housing of the apparatus 10 is elongate in shape and has a proximal end via which light is emitted from the illuminating device 1. The overall length of the housing is about 15cm.

The apparatus 10, in use, is placed against the skin with the illuminating device 1 being positioned so as to direct radiation towards the affected area. Before operation the apparatus is programmed to set the duration of the radiation and the power of radiation. In this embodiment the apparatus is set to provide a single pulse of light energy lasting 1 second that delivers  $1.5 \text{ Jcm}^{-2}$  to the 6mm diameter spot. The peak power output of the illuminating device 1 is below  $5\text{W/cm}^{-2}$ . The energy profile over time of the radiation delivered is such that the energy is continuously delivered during the 1 second pulse and is such that during any period of  $10\mu\text{s}$  the light energy delivered is less than  $0.5 \text{ Jcm}^{-2}$  and such that during any period of 100ms the

light energy delivered in is less than  $5 \text{ Jcm}^{-2}$ . The method of this embodiment relies solely on photochemical effects that occur within the skin as is explained in further detail below. In general, it is preferable that the method of the invention is so performed that, and/or the apparatus of the invention is so arranged that in normal use, there is substantially no beneficial photo-thermal reaction caused within the skin.

The radiation received by the skin 11 causes a photochemical reaction in Porphyrin in the skin that releases singlet oxygen (a free radical), which then destroys at least some of the bacteria, which is one of the causes of the symptoms of acne. The radiation received is however well below the level at which erythema may be induced. The radiation emitted by the illuminating device includes light having an intensity that peaks at a wavelength of about 585nm and includes components of light radiation having wavelengths in the range of 570-600nm. Such wavelengths are suitable for targeting the porphyrin in the skin layers at a depth sufficient for causing the released reactive oxygen to affect the Propionibacterium acnes bacteria without significantly affecting other tissues.

The illuminating device includes a plurality of LEDs 7 arranged in a 2-D array 2 (shown schematically in Figure 2 as LEDs arranged in a close-packed formation) connected to a lens arrangement (not shown) that focuses the radiation emitted by the LEDs, so that a concentrated source of light is provided. The device 1 is therefore suitable for "spot treatment" of skin condition (i.e. treating small areas one at a time). Figure 3 shows other components of the illuminating device 1, such other components being provided to cool the LEDs.

Referring to the Fig. 3, there is shown illuminating device (generally designated 1) comprising, in sequence, an LED diode array 2, a high thermal conductivity heat spreader layer 3, a



Peltier type thermoelectric cooler 4 and a heat pipe arrangement 5 (including a distal condenser 6).

5 The heat spreader 3, thermoelectric cooler 4 and heat pipe arrangement 5 are provided to keep the operating temperature of the LEDs at a reduced level and therefore operating most efficiently. It is well-known that the efficiency of an LED increases with reduced operating temperature and in the case of LEDs operating at wavelengths between 550nm and 650nm this dependence on temperature is very high.

10 Heat flowing from the LED diode array 2 is spread over a larger area by the high conductivity spreader layer 3. This layer is typically only a few millimetres thick and provides rapid and highly efficient heat transfer away from the diode array 2. Heat then flows into the cold end of the thermoelectric  
15 Peltier cooler 4. The hot end of the thermoelectric Peltier cooler layer 4 is in heat transfer coupling with the heat pipe 5. The high thermal conductivity layer 3 includes a diamond material, which is laid down by means of a plasma/chemical vapour deposition method.

20 The Peltier cooler 4 includes a separate control means including associated drive circuitry which accurately controls, during use, the heat transfer away from the LED diode array 2 via the high thermal conductivity spreader layer 3. Accurate control of the driven Peltier thermoelectric cooler 4 (in combination  
25 with the provision of the high thermal conductivity heat spreader layer 3 and the downstream heat pipe cooling arrangement 5) provides for extremely efficient thermal management of the apparatus, and in particular the diode array 2, which ensures consistency of the light output.

30 The heat pipe arrangement 5 includes a wick to direct fluid coolant (contained in the heat pipe arrangement 5) away from the "hot zone" via capillary action, gravity or diffusion. The

arrangement includes a fluid return system to return cooled fluid from the "cold zone" at the distal end of the apparatus, which is provided with a condenser 6. The condenser 6 is itself cooled by air cooling.

5       The treatment of Acne using this method has been / will be trialled on patients suffering from facial acne. The illuminating device used in these trials was in the form of a small spot illuminating device (as described above). During the trials, the radiation emitted during a single dose was about  
10   1.5J/cm<sup>-2</sup> for a 6mm spot size. Trials are also planned with the use of the illuminating device similar to that described above but being in the form of a larger 2-D array of such devices. Such an array of devices would for example be suitable for illumination and treatment of larger areas such as the face or  
15   back. The results of the initial trials appear to demonstrate a beneficial effect on the skin conditions treated.

It will be appreciated that various modifications may be made to the above-described embodiments of the invention without departing from the spirit of the invention. For example, the  
20   illuminating device used may be in the form of any illuminating device able to produce controlled doses of radiation at appropriate energy levels and wavelengths, without exceeding certain power levels. For example, the illuminating device may be in the form of a line of a plurality of the illuminating  
25   devices described above (a "line treatment") or could be in the form of the 2-D array of devices as proposed for use in the trials (a "wide area treatment"). There may also be provided a lower fluence device for spot treatment or for line treatment that can be used to "top-up" the higher dosage spot treatment  
30   described above. Such a low fluence device would be particularly suitable for home-use.

In the embodiment described above, the wavelength of radiation used is in the range 570-600nm. However, other embodiments are envisaged that target other peaks in the porphyrin absorption within the skin tissue. Thus, for example  
5 light radiation having wavelengths in the violet/near ultra-violet light, blue, green and red wavelength bands could also be used, either individually, or in various combinations. The light could be emitted from a single apparatus (possibly from a single illuminating device) or by separate apparatuses. The control  
10 unit would of course control the relative levels of light for the different colours to deliver differing amounts of reactive light at different depths in the skin - thereby tailoring the proposed treatment dependent on the depth of infection by the *Propionibacterium acnes* bacteria.

**CLAIMS**

1. An apparatus for the treatment of a skin condition comprising

5       an illuminating device, and  
      a control unit for controlling the operation of the illuminating device, wherein

      the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and  
10       wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by a skin condition, which reaction would result in agents causing the skin condition being at least partially disabled or destroyed, and

      the control unit and illuminating device are so arranged and  
15       configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:

      the light energy received at said area during a period of at  
20       least 100ms is at least  $0.01\text{Jcm}^{-2}$ ,

      the light energy received at said area in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ , and

      the light energy so delivered in any given period of 100ms is less than  $5\text{Jcm}^{-2}$ , whereby

25       the apparatus may be used to treat the skin condition.

2. An apparatus according to claim 1, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the  
30       single dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during

the single dose being greater than  $0.1 \text{ Jcm}^{-2}$  and being equal to  $T_1 \times P_1$ , where  $T_1$  = the length in time of the single dose and  $P_1$  has the units of optical power density (power per unit area) and satisfies  $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$ .

- 5 3. An apparatus according to claim 1, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10  
10 seconds and the energy of the light radiation delivered during the single dose being equal to  $T_2 \times P_2$ , where  $T_2$  = the length in time of the single dose and  $P_2$  has the units of optical power density (power per unit area) and satisfies  $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$ .
- 15 4. An apparatus according to claim 2 or claim 3, wherein the apparatus is so configured and arranged that, during a single dose of light radiation, an area of skin of between 12 and  $200 \text{ mm}^2$  is treated.
- 20 5. An apparatus according to claim 1, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10 hours, light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than  $0.1 \text{ Jcm}^{-2}$  and being equal to  
25  $T_3 \times P_3$ , where  $T_3$  = the length in time of the single treatment and  $P_3$  has the units of optical power density (power per unit area) and satisfies  $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$ .
- 30 6. An apparatus according to claim 5, wherein the apparatus is so configured and arranged that, during a single treatment, an area of skin of between  $0.003$  and  $0.5 \text{ m}^2$  is treated.

7. An apparatus according to any preceding claim, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between 570nm and 600nm.

8. An apparatus according to any preceding claim, wherein the  
5 illuminating device is arranged to provide light radiation including radiation having a wavelength between 390nm and 420nm.

9. An apparatus according to any preceding claim, wherein the illuminating device comprises one or more light emitting semiconductor devices.

10 10. An apparatus according to claim 9, wherein the or each semiconductor device is in the form of a diode.

11. Use of an apparatus according to any preceding claim, including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an  
15 energy such that an area of at least  $12\text{mm}^2$  receives energy from the illuminating device during a period of at least 100ms of at least  $0.01\text{Jcm}^{-2}$ , the radiation including radiation having a wavelength of between 570 nm and 600 nm, the energy received from the illuminating device at said area in any given period of  $10\mu\text{s}$   
20 being less than  $0.5\text{Jcm}^{-2}$ , and the energy received from the illuminating device in any given period of 100ms being less than  $5\text{Jcm}^{-2}$ .

12. A method of improving the cosmetic appearance of a region of skin by means of conducting the non-therapeutic steps of  
25 providing an illuminating device, and operating the illuminating device to direct light radiation on to the region of skin, wherein during a period of at least 100ms, said region receives light energy from the illuminating device of at least  $0.01\text{Jcm}^{-2}$ ,  
30 the light energy so delivered in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ , and

the light energy so delivered in any given period of 100ms is less than 5 Jcm<sup>-2</sup>.

13. A method according to claim 12, wherein the light energy so delivered causes photochemical reaction within an area of skin  
5 affected by a skin condition, the reaction at least partially disabling or destroying bacteria contributing to the symptoms of the skin condition.

14. A method for the cosmetic treatment of Acne Vulgaris comprising the steps of

10 providing an illuminating device, and  
operating the illuminating device to direct light radiation on to an area of skin affected by Acne Vulgaris, wherein  
during a single treatment, lasting at least 100ms, said area receives light energy from the illuminating device of at least  
15 0.01Jcm<sup>-2</sup>,

the light energy so delivered in any given period of 10μs is less than 0.5 Jcm<sup>-2</sup>,

the light energy so delivered in any given period of 100ms is less than 5 Jcm<sup>-2</sup>, and

20 the light energy so delivered causes a photochemical reaction within the affected skin which at least partially disables or destroys bacteria contributing to the symptoms of Acne Vulgaris.

15. A method according to claim 13 or claim 14, wherein the  
25 photochemical reaction stimulates the production of free-radicals, which then react with, and at least partially disable or destroy, agents causing the skin condition.

16. An apparatus according to any of claims 1 to 11, wherein the apparatus is arranged and configured so as to be suitable for use  
30 in the method as claimed in any of claims 12 to 15.

17. An apparatus substantially as herein described with reference to any of the accompanying drawings.



**Amendments to the claims have been filed as follows**

- 
1. An apparatus for the cosmetic treatment of a skin condition comprising
- an illuminating device, and
  - a control unit for controlling the operation of the illuminating device, wherein
- the illuminating device is so arranged and configured that it is able in use to emit light radiation of an energy and wavelength profile sufficient to cause a photochemical reaction within an area of skin affected by the skin condition, which reaction would result in agents causing the skin condition being at least partially disabled or destroyed and the illuminating device is so arranged and configured so that, in use, substantially no beneficial photo-thermal reaction occurs within the said area of skin, and
  - the control unit and illuminating device are so arranged and configured that the control unit is able in use to cause the illuminating device to direct light radiation on to an area within a distance of no more than 1000mm from the illuminating device such that:
    - the light energy received at said area during a period of at least 100ms is at least  $0.01\text{Jcm}^{-2}$ ,
    - the light energy received at said area in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ , and
    - the light energy so delivered in any given period of 100ms is less than  $5\text{Jcm}^{-2}$ , whereby
  - the apparatus may be used to treat the skin condition.

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2. An apparatus as claimed in claim 1, wherein said skin condition is Acne Vulgaris.

3. An apparatus according to claim 1 or claim 2, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during the single dose being greater than  $0.1 \text{ Jcm}^{-2}$  and being equal to  $T_1 \times P_1$ , where  $T_1$  = the length in time of the single dose and  $P_1$  has the units of optical power density (power per unit area) and satisfies  $0.2 \text{ Wcm}^{-2} < P_1 < 20 \text{ Wcm}^{-2}$ .

4. An apparatus according to claim 1 or claim 2, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to cause the illuminating device to deliver a single dose of light radiation to an area of skin, the single dose being provided over a period of between 200ms and 10 seconds and the energy of the light radiation delivered during the single dose being equal to  $T_2 \times P_2$ , where  $T_2$  = the length in time of the single dose and  $P_2$  has the units of optical power density (power per unit area) and satisfies  $0.01 \text{ Wcm}^{-2} < P_2 < 1 \text{ Wcm}^{-2}$ .

5. An apparatus according to claim 3 or claim 4, wherein the apparatus is so configured and arranged that, during a single dose of light radiation, an area of skin of between  $12$  and  $200 \text{ mm}^2$  is treated.

- 30 -

6. An apparatus according to claim 1 or claim 2, wherein the control unit and illuminating device are so configured and arranged that the control unit is able in use to deliver, during a single treatment lasting between 300ms and 10 hours, light radiation to an area of skin, the energy of the light radiation delivered during the single treatment being greater than  $0.1 \text{ Jcm}^{-2}$  and being equal to  $T_3 \times P_3$ , where  $T_3$  = the length in time of the single treatment and  $P_3$  has the units of optical power density (power per unit area) and satisfies  $0.5 \text{ mWcm}^{-2} < P_3 < 500 \text{ mWcm}^{-2}$ .

7. An apparatus according to claim 6, wherein the apparatus is so configured and arranged that, during a single treatment, an area of skin of between  $0.003$  and  $0.5 \text{ m}^2$  is treated.

8. An apparatus according to any preceding claim, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between  $570 \text{ nm}$  and  $600 \text{ nm}$ .

9. An apparatus according to any preceding claim, wherein the illuminating device is arranged to provide light radiation including radiation having a wavelength between  $390 \text{ nm}$  and  $420 \text{ nm}$ .

10. An apparatus according to any preceding claim, wherein the illuminating device comprises one or more light emitting semiconductor devices.

11. An apparatus according to claim 10, wherein the or each semiconductor device is in the form of a diode.

12. Use of an apparatus according to any preceding claim, including illuminating a surface within a distance of no more than 1000mm from the illuminating device with radiation of an energy such that an area of at least  $12\text{mm}^2$  receives energy from the illuminating device during a period of at least 100ms of at least  $0.01\text{Jcm}^{-2}$ , the radiation including radiation having a wavelength of between 570 nm and 600 nm, the energy received from the illuminating device at said area in any given period of  $10\mu\text{s}$  being less than  $0.5\text{Jcm}^{-2}$ , and the energy received from the illuminating device in any given period of 100ms being less than  $5\text{Jcm}^{-2}$ .

13. A method of improving the cosmetic appearance of a region of skin by means of conducting the non-therapeutic steps of

providing an illuminating device, and  
operating the illuminating device to direct light radiation on to the region of skin, wherein

during a period of at least 100ms, said region receives light energy from the illuminating device of at least  $0.01\text{Jcm}^{-2}$ ,

the light energy so delivered in any given period of  $10\mu\text{s}$  is less than  $0.5\text{Jcm}^{-2}$ , and

the light energy so delivered in any given period of 100ms is less than  $5\text{Jcm}^{-2}$ , wherein the light energy so delivered causes photochemical reaction within an area of skin affected by a skin condition, the reaction at least partially disabling or destroying bacteria contributing to the symptoms of the skin condition, and wherein the light

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energy so delivered causes substantially no beneficial photo-thermal reaction to occur within the said area of skin.

14. A method as claimed in claim 13, wherein said light radiation is directed on to an area of skin affected by Acne Vulgaris and

the light energy so delivered causes a photochemical reaction within the affected skin which at least partially disables or destroys bacteria contributing to the symptoms of Acne Vulgaris.

15. A method according to claim 13 or claim 14, wherein the photochemical reaction stimulates the production of free-radicals, which then react with, and at least partially disable or destroy, agents causing the skin condition.

16. An apparatus according to any of claims 1 to 12, wherein the apparatus is arranged and configured so as to be suitable for use in the method as claimed in any of claims 13 to 15.

17. An apparatus substantially as herein described with reference to any of the accompanying drawings.



**Application No:** GB 0301740.7  
**Claims searched:** 1 to 17

**Examiner:** Matthew Parker  
**Date of search:** 3 July 2003

## Patents Act 1977 : Search Report under Section 17

### Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1, 3-7, 9-16	EP 0726083 A2 (ESC), see page 6, lines 18 to 21
X	1-6, 8-10 12-16	US 2002/0161418 (WILKENS), see page 2, paragraph [0020]
A		GB 2368020 A (ICN)

### Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

### Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC<sup>v</sup>:

A5R

Worldwide search of patent documents classified in the following areas of the IPC<sup>7</sup>:

A61N

The following online and other databases have been used in the preparation of this search report :

Online: EPODOC, JAPIO, WPI